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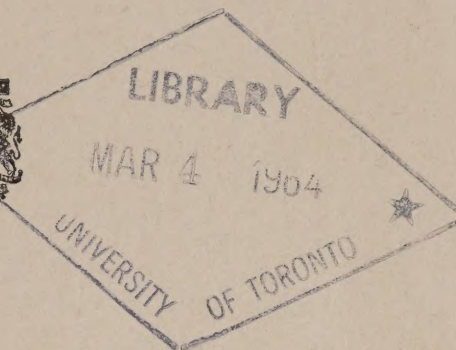
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RESTRICTIVE TRADE PRACTICES COMMISSION

REPORT

CONCERNING THE MANUFACTURE,
DISTRIBUTION AND SALE OF DRUGS

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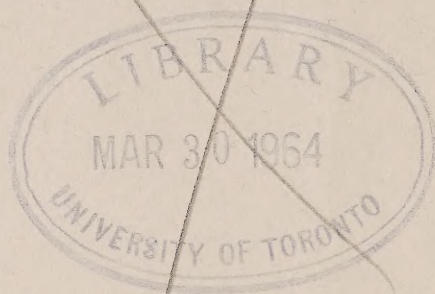
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RESTRICTIVE TRADE PRACTICES COMMISSION

REPORT

CONCERNING THE MANUFACTURE,
DISTRIBUTION AND SALE OF DRUGS

Pierre Carignan, Q.C., M.A., M.B.A.
Member

COMBINES INVESTIGATION ACT

Ottawa
1963

RESTRICTIVE TRADE PRACTICES COMMISSION

Pierre Carignan, Q.C., M.A., LL.L.
Member

RESTRICTIVE TRADE PRACTICES COMMISSION

OTTAWA

January 24, 1963.

Honourable Donald M. Fleming, P.C., Q.C., M.P.,
Minister of Justice,
Ottawa.

Sir:

As the sole member of the Commission, I have the honour to present to you the report of the Restrictive Trade Practices Commission arising out of a general inquiry made under section 42 of the Combines Investigation Act into the subject of the manufacture, distribution and sale of drugs.

This inquiry was started on April 14, 1958 by Mr. T.D. MacDonald, Q.C., then Director of Investigation and Research, and continued by his successor Mr. D.H.W. Henry, Q.C. The material collected was summarized in a document described in this report as the Green Book and submitted to the Commission on February 28, 1961.

To secure all possible additional information, the Commission after due notice conducted public hearings throughout the summer and fall of 1961 in Ottawa, Halifax, Winnipeg, Regina, Edmonton, Calgary, Vancouver, Victoria, Toronto and Montreal and a final public hearing in Ottawa in November, 1961. All these hearings were held before Mr. C. Rhodes Smith, Q.C., M.A., LL.B., B.C.L., Chairman, Mr. A.S. Whiteley, M.A., Member, and the undersigned.

Throughout the hearings, the Commission received the full co-operation of all participants, whether they appeared in their individual capacities or as representatives of business, consumer, professional or other organizations. Mr. F.N. MacLeod, representing the Director of Investigation and Research, greatly assisted the Commission in eliciting the full purport of all statements and arguments presented to the Commission. The sincerity of the witnesses and, in many cases, the obvious care expended in the preparation of

briefs impressed the Commission favourably. The facts disclosed and the arguments advanced have facilitated its task of appraising a very complex situation.

The Commission is particularly indebted to the former members, Messrs. C. Rhodes Smith and A.S. Whiteley, whose terms of office expired at the end of October 1962, before this report had been completed. In accordance with arrangements made pursuant to the proposal announced by you in the House of Commons on October 23, 1962, and approved by the Governor in Council under sections 24 and 25 of the Combines Investigation Act, Mr. Smith and Mr. Whiteley were retained in the capacity of special assistants to assist the Commission in completing the report. As a result of these arrangements, they participated throughout in the preparation of the report and since the end of October, 1962 have devoted themselves exclusively to this task. I am authorized to say that they agree with all the conclusions and recommendations contained in the report.

Yours faithfully,

(Sgd.) Pierre Carignan

Pierre Carignan
Member

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CHAPTER I

ORIGIN AND NATURE OF THE INQUIRY

1. Reference to the Restrictive Trade Practices Commission

This inquiry was brought before the Restrictive Trade Practices Commission by the Director of Investigation and Research pursuant to section 42 of the Combines Investigation Act, R.S.C. 1952, Chapter 314, the terms of which are as follows:

"42. (1) The Director upon his own initiative may and upon direction from the Minister or at the instance of the Commission shall carry out an inquiry concerning the existence and effect of conditions or practices having relation to any commodity which may be the subject of trade or commerce and which conditions or practices are related to monopolistic situations or restraint of trade, and for the purposes of this Act any such inquiry shall be deemed to be an inquiry under section 8.

(2) It is the duty of the Commission to consider any evidence or material brought before it under subsection (1) together with such further evidence or material as the Commission considers advisable and to report thereon in writing to the Minister, and for the purposes of this Act any such report shall be deemed to be a report under section 19."

The Director submitted to the Commission on February 28, 1961 a statement relating to the manufacture, distribution and sale of drugs. This statement, hereinafter sometimes referred to as the Green Book, ⁽¹⁾ describes as follows the subject-matter of the inquiry:

"4. The inquiry relates to the sale and distribution of drugs generally and information was obtained about most aspects of the drug industry. However, to keep the inquiry

(1) Appendix Q to this Report.

within manageable limits, detailed information about costs, markups, selling prices and similar aspects was obtained about two general types of drugs only - the antibiotic drugs and the tranquilizer or ataraxic drugs*. These drugs were chosen because they are the two most widely-used types of ethical drugs and because they are the types in respect of which most complaints were received. The choice of these drugs seems to have been fortunate because the information obtained about these drugs appears to illustrate conditions in the drug field generally. This is because these drugs range from new, patented, closely-controlled drugs to older, non-patented drugs which are available from many sources to any drug manufacturer or distributor which wishes to deal in them.

. . .

6. This inquiry is concerned principally with ethical drugs rather than proprietary drugs (these terms are explained more fully below). Sales of ethical drugs are subject to various restrictions and differ from sales of ordinary commodities in several ways. Sales of proprietary drug products, on the other hand, are similar to sales of most other commodities. These products are advertised to the public, there are normally many types of similar products available to the purchaser, and the purchaser is free to choose whichever he pleases. Proprietary drugs will be referred to in the Statement, but the main emphasis will be on ethical drugs and the situation in the ethical drug field.

* Information about selling prices was obtained by securing price lists from various manufacturers and distributors. This material contains particulars of selling prices, discounts and the like, for the other pharmaceutical products of such manufacturers and distributors, as well as for antibiotic and ataraxic drug products."

(Green Book, pp. 1-3)

It is the duty of the Commission to study the submission made by the Director together with other evidence deemed advisable and to report thereon to the Minister of Justice. It must be pointed out however that a report under section 42 is of a general character and should be distinguished from a report arising from an inquiry into alleged contraventions of the anti-combines legislation.

2. Initiation of the Investigation and Compilation
of Information by the Director of
Investigation and Research

In describing the initiation of the inquiry, the Director of Investigation and Research stated:

"2. Following informal complaints about the high cost of drugs, the Director made preliminary inquiries about the sale and distribution of drugs in Canada to determine if a formal inquiry under the Combines Investigation Act was warranted. These preliminary inquiries did not indicate that any price-fixing arrangements existed, but they did indicate that patents are used in such a way as to limit the number of firms engaged in the manufacture and sale of particular drugs; that prices of certain drugs are extremely high in relation to cost of manufacture; that such prices have in some cases remained unchanged for several years despite increased production and use of the particular drug; that there is marked uniformity of pricing among manufacturers; and that, both because of conditions peculiar to the drug field and because of the practices of firms in the field, there is only limited price competition in the supplying of drugs to the public. In view of this preliminary information, the Director started a formal inquiry under section 42 of the Combines Investigation Act on April 14, 1958."

(Green Book, p. 1)

The Green Book is a volume of almost 300 pages in which were incorporated the results of the Director's inquiries. It is entitled "Material Collected for Submission to the Restrictive Trade Practices Commission in the Course of an Inquiry under Section 42 of the Combines Investigation Act Relating to the Manufacture, Distribution and Sale of Drugs". As emphasized in its preface, the Green Book is not a report under the Combines Investigation Act, but a statement of material collected and analysed by the Director for the purpose of being laid before the Commission in the course of an inquiry under section 42 of the Act.

As the sources of the material compiled by the Director are described in the Green Book (pp. 3-5), they need not be detailed here.

3. Steps Taken by the Restrictive Trade Practices Commission to Obtain Submissions

In March, 1961, the Restrictive Trade Practices Commission wrote to the 146 manufacturers and distributors of drugs whom the Director of Investigation and Research had requested to supply information⁽¹⁾. Advice was given to them that the Commission had the duty of considering the material compiled by the Director together with such other evidence and material as might be deemed advisable and reporting thereon to the Minister of Justice. The Commission enclosed a copy of the Green Book with its letter, which concluded:

"If, after considering the material collected and analysed by the Director, you are of the opinion that you will wish to present a written brief or to make submissions in connection with this inquiry to the Commission, will you so inform the Commission at the earliest possible date. Will you also indicate the form in which you wish to make representations, that is written or oral submissions or both, and the date when you believe you will be ready to make your submissions to the Commission."

Approximately 80 similar invitations were also sent with copies of the Green Book to professional, trade and hospital associations, health and welfare organizations, schools of social work in universities across Canada, Provincial Departments of Health, and also to other persons, institutions, organizations and associations interested in the subject of the inquiry, including the Connaught Medical Research Laboratories, the Canadian Association of Consumers (now Consumers Association of Canada) and the Canadian Federation of Agriculture.

The Commission desired to obtain in this way all possible additional information and views which would be of assistance in preparing its report.

4. Public Hearings Held by the Restrictive Trade Practices Commission

In response to the invitations of the Commission a number of persons, companies and organizations indicated that they wished to make representations to the Commission. After having carefully considered all representations made to him, the Chairman of the Commission

(1) These firms are identified by an asterisk before their names in Appendix I to the Green Book.

came to the conclusion that the public interest would best be served by conducting in public all hearings in this inquiry. Accordingly, on June 14, 1961, he made an order to this effect under section 28 of the Combines Investigation Act⁽¹⁾. The Commission also decided to hold hearings in the following cities where there was reason to believe that the attendance of interested persons and organizations would justify the holding of a session: Ottawa, Halifax, Winnipeg, Regina, Edmonton, Calgary, Vancouver, Victoria, Toronto and Montreal. An announcement was made by press release of the time and place of the hearings to ensure that such information would be available to anyone interested in making representations. The dates of the hearings in the various cities were as follows: Ottawa, July 4-6; Halifax, July 10-11; Winnipeg, July 17-18; Regina, July 20; Edmonton, July 24; Calgary, July 27; Vancouver, July 31; Victoria, August 3; Montreal, October 2; Toronto, October 16-20 and 23-27 and Ottawa, November 28-29.

In all, public hearings were held on 25 days and the transcript of the proceedings ran to 3260 pages. Voluminous exhibits were also filed. The Commission received representations at the hearings from various organizations, companies and individuals. A list of counsel who appeared at the hearings and a list of witnesses and other appearances will be found in Appendices O and P respectively. The Commission also received numerous written representations from individuals or organizations that were not represented at the hearings.

(1) See Appendix A to this Report.

CHAPTER II

PHARMACEUTICAL NOMENCLATURE

1. The Chemical Name

As indicated in the Green Book, a drug may be designated by various types of names. Firstly the chemical name of a drug reveals its chemical composition. On this subject, Dr. Lloyd C. Miller, Director of Revision of the U.S. Pharmacopeia, wrote the following:

" . . . When first synthesized, or when first identified if derived from a natural source, a potentially useful compound receives a systematic chemical name. To be adequate and fully specific, this name must reveal every part of the compound's molecule, including any and all forms of isomerism if present, and must be such that it can describe only the compound concerned and no other. The systematic chemical name is generally so formidable that even chemists, especially those concerned with the synthesis of organic medicinal compounds, have little patience with it and tend to coin 'trivial' names to abbreviate the names for specific compounds or groupings. Although examples of trivial names are numerous, citing one suffices to illustrate the advantages of their use. Chemically, phenol is hydroxybenzene or hydroxycyclohexatriene; yet how many recognize at once that the 'trivial' name and the 2 systematic names are synonymous?"⁽¹⁾

In addition to being cumbersome, the chemical names present the following inconveniences, according to Dr. Miller:

" . . . First, the rules of chemical nomenclature are such that most complex drugs of today can be correctly represented by several chemical names, some of which may very well obscure the true nature of the compound.

(1) Lloyd C. Miller, "Doctors, Drugs, and Names", The Journal of the American Medical Association, Vol. 177, No. 1, July 8, 1961, Therapeutic Number, p. 27.

For example, ethyl alcohol may properly be called ethanol, hydroxyethane, methylcarbinol, or hydroxymethylmethane. Second, the use of the chemical name fails to convey needed information to the very person who requires it most, i. e., the physician who is to prescribe the drug. It is not unfair to say that few physicians are sufficiently conversant with organic chemistry to be able to recognize a compound by its chemical name. Indeed, this may be said also of most pharmacists and pharmacologists who deal with today's drugs. . . ."⁽¹⁾

In his evidence before the Commission Dr. Nathan Schechter, a practising physician and Chairman of the Pharmacy Committee of the Ottawa Civic Hospital, referred to the chemical name as "a very long, lengthy, very wordy affair that only a chemist would understand" (Hearing, p. 259). Again, Dr. J. P. Gemmell, Associate Professor of Medicine at the University of Manitoba, described it as "almost unintelligible except to the very ultra-specialist in the field" (Hearing, p. 507). Finally the brief submitted by The Canadian Pharmaceutical Association, Inc.⁽²⁾ stated it is "usually too unwieldy for everyday use" (Association brief, p. 38; Hearing, p. 2377).

2. The Proper Name

Drugs which are either single chemical compounds or natural aggregates of substances such as extracts of plant and animal origin may also have a proper name, which is the name recognized in the Food and Drug Regulations⁽³⁾, in a licence issued under section 12 of the Food and Drugs Act⁽⁴⁾ or in any of the official reference books on drugs⁽⁵⁾.

(1) Ibid., p. 32.

(2) In this Report this Association is sometimes referred to as C. Ph. A.

(3) Appendix C to this Report, Food and Drug Regulations, C. 01. 001 (j).

(4) Appendix B to this Report, Food and Drugs Act, s. 12; Appendix C to this Report, Food and Drug Regulations, C. 03. 001 (b) and C. 04. 001 (c).

(5) Appendix B to this Report, Food and Drugs Act, Schedule B.

With respect to proper names, Mr. Grant L. Kalbfleisch, Secretary of the Canadian Drug Advisory Committee, has written:

"The use of the term 'proper name' is distinctly Canadian and to my knowledge it first appears in the office consolidation of the Food and Drugs Act and Regulations of 1949. However, it was not adopted by other countries. At the present time the 'New and Nonofficial Remedies' appear to use the term 'generic name' as a synonym. The various pharmacopoeias use the term 'pharmacopoeial name' and the British Pharmacopoeia Commission uses the term 'approved name' for some drugs not listed in the British Pharmacopoeia. The World Health Organization uses the term 'international non-proprietary name'. Each of these terms seems to fit the particular case in which it is used, but for all intents and purposes they are proper names. The two main characteristics of proper names which are common in all of these are that they must have official status and must be in the public domain. . . ."⁽¹⁾

While the term "proper name" is distinctly Canadian, the term "generic name", imported from the United States, is currently used as a synonym. However, this is a misnomer, as pointed out by Mr. P.G. Stecher:

". . . The adjective generic obviously comes from the latin word genus and suggests classification into genera as is the practice in botany and zoology. Actually the term is a misnomer as used in the drug field. The generic name does not relate to a class or genus of drugs; it denotes a single drug. Generic here is taken as opposed to specific. Specific applies to the trademark (also called brand or proprietary name) which is specific to one sole owner, while the generic name is nonproprietary. The term non-proprietary is more accurate and descriptive, but generic sounds better, is shorter and easier to pronounce--and so will probably stay with us for a long time to come, although it is a contradictory term. It most decidedly does not describe a genus or kind of products common to all the pharmaceutical trade. It does denote or should denote a unique substance definable in chemical nomenclature as a single chemical compound not to be confused with any other substance of the same kind or belonging in the same group

(1) Grant L. Kalbfleisch, "Pharmaceutical Nomenclature", Canadian Pharmaceutical Journal, Vol. 86, No. 1, January 1, 1953, pp. 12-16 at p. 12.

of drugs. This definition has been broadened to allow the coining of generic names for natural aggregates of substances such as extracts of plant or animal origin, but excludes proprietary mixtures where each component has its own generic name."⁽¹⁾

When many firms market the same drug each under a brand name of its own, the need for a proper name is obvious. With respect to the desirable attributes of the words selected as proper names, let us refer again to Dr. Lloyd C. Miller:

"Without entering into debate on the merits of prescribing exclusively by 'generic' or nonproprietary names, it is self-evident that the convenience of all is served best when the nonproprietary names are as short and pronounceable as possible. Yet there is equal agreement on the proposition that the name should point up such relationships as exist among compounds that fall into a common pharmacological group. This mitigates [sic] against brevity and, indeed, leads directly to names that have been criticized for their length. Such is the case of the group of antibiotics, the parent member of which was named tetracycline. Adoption of that name logically led to the already known chlortetracycline and oxytetracycline, both available as the hydrochloride salt. There followed, as a result of commendable research, rolitetracycline, a pyrrolidine derivative, and demethylchlortetracycline, by the removal of a methyl group from chlortetracycline. Syllable-counters have a heyday with the hydrochloride of demethylchlortetracycline particularly; yet it fits logically into the pattern of the first names chosen. In retrospect, it might have helped to have picked tecline, or tycline, or some other available one - or two-syllable name for the parent molecule; but the object at the time was to convey the newly-found information that this compound consisted of 4 benzene rings which an accommodating strain of actinomyces had lined up like soldiers four-abreast in a new and exciting molecule. This discussion makes it obvious that a choice has to be made between meaningless short names and longer names that convey helpful information."⁽²⁾

(1) Paul G. Stecher, "Generic Names of Drugs", Journal of Chemical Education, Vol. 34, No. 9, September, 1957, p. 454.

(2) Miller, op. cit., pp. 29-30.

As Canada is far from being self-contained with regard to drug production, any attempt to assign proper names which would be distinctly Canadian would create confusion. For this reason, Canada is interested in the steps that are taken abroad to promote the early selection of appropriate generic names on an international level. This aspect of the problem has been stressed in the evidence given before the Commission by:

(1) Dr. Mark Nickerson, Professor and Head of the Department of Pharmacology and Therapeutics at the University of Manitoba:

"THE CHAIRMAN: What is the practice of doctors prescribing here, between trade names and generic names? Do they give the trade name and the company under the generic name?

DR. NICKERSON: I think 90% of the cases is to write simply the trade name and nothing else.

There are reasons for this, and in an area which I think some action is indicated, the generic name, there is no really official procedure for setting up generic names in Canada. By and large, the generic names accepted by the Council of Pharmacy of the American Medical Association is accepted. The naming of drugs with the numbers coming up is quite a problem. There are not that many words in the English language, and it has been impossible under the terms on which they were working for this Committee to select generic names. This is consequently, the legal procedure is to have the manufacturer submit a trade name and two suggested generic names. This has become, the selection of names, quite an argument in the pharmaceutical industry, and the art at the moment seems to be to select a trade name which is catchy and easy to remember, and to select generic names which are as difficult as possible to remember.

One example which has been on the market for some little time is Diamox. The generic name is acetazolamide. Another example is a muscle relaxer called Flexon. The generic name is zoxazolamine. There seems to be a real attempt to make generic names as hard as possible to remember."

(Hearing, pp. 550-52)

(2) J.L. Summers, Associate Professor of Pharmacy at the University of Saskatchewan and Director of the Pharmaceutical

Services at the University Hospital:

"MR. WHITELEY: With respect to the recommendation regarding naming of drugs, do you think it is possible for Canada alone to proceed along the course you suggest?

PROF. SUMMERS: It would be possible. How practical it would be is another thing. Knowing as you well do, sir, that we are more or less the meat in the sandwich between what happens in Great Britain and what happens in the United States, and we are faced right now with drugs with two official names.

I am thinking of the drug marketed under the trade name Demerol, which is an analgesic preparation, which in the British Pharmacopoeia is called Pethidine, and this in the United States Pharmacopoeia is called Piperidine Hydrochloride⁽¹⁾. Perhaps the addition of another name would merely muddy the water.

Also you must take into consideration that the World Health Organization is attempting to introduce some degree of agreement on generic names. The only problem is what they eventually produce is a compromise and usually is completely unsuitable in that it does not meet the requirements we have specified.

. . .

PROF. SUMMERS: . . . we have found where a generic or where a non-proprietary name has been used very early in the development of a drug and a great deal of investigation has taken place on this drug and has been reported in the literature using non-proprietary terminology, that the physician only knows and writes the non-proprietary terminology for this drug.

Immediately one thinks of drugs like Cortisone; how many prescriptions come in with proprietary names for Cortisone? The majority we get are for cortisone, which is the official name of the drug. The same thing is true of Bacitracin and Neomycin, and in a number of drugs which had more or less a long-development period.

In order for a name to gain wide acceptance and understanding by the medical profession, it would be necessary for it to appear in the literature with sufficient frequency that they would become familiar with it. It is quite true that our medical literature today is largely either

(1) This seems to be an error. From other evidence given by Professor Summers, it seems that he is referring to meperidine hydrochloride (Hearing, p. 907).

American or British, and we would be influenced by their nomenclature. . . ."

(Hearing, pp. 2230-32)

With respect to the naming of drugs, Mr. Kalbfleisch has written:

"The most conspicuous flaw in the old system was that drugs had to achieve pharmacopoeial status before there was an official name. Therefore, until the drug was accepted for inclusion in a pharmacopoeia it was sold under any name, usually a brand name with a chemical explanation. On adoption of the drug by the pharmacopoeia, the brand name could not be recognized because it was the property of the sponsor, and the chemical name usually was too cumbersome. This left the pharmacopoeial authorities with the prospect of devising a new name which would have to compete with one under which the product had already been promoted and was known.

From 1948 to the present time there has been a departure from the old system in that three bodies, namely, the Council on Pharmacy and Chemistry^[1] of the American Medical Association^[2] who publish New and Nonofficial Remedies^[3], the British Pharmacopoeia Commission, and the World Health Organization, all publish generic, approved or non-proprietary names for some drugs in advance of actual acceptance of the monographs to appear in the respective volumes. When these names are used with the proprietary or brand name at the time of introduction to the market much confusion is eliminated.

[1] Now called the Council on Drugs.

[2] The American Medical Association and the United States Pharmacopoeia have recently joined forces in a program of selection of nonproprietary names for single entity drugs. See "New Names," The Journal of the American Medical Association, Vol. 178, No. 7, November 18, 1961, p. 162.

[3] Now called New and Nonofficial Drugs.

The general principles stated for guidance in devising the names which would be acceptable to the World Health Organization and to the British Pharmacopoeia Commission are very similar. In fact, the first six points as listed below are identical.

1. Names should, preferably, be free from any anatomical, physiological, pathological or therapeutic suggestion.
2. An attempt should first be made to form a name by the combination of syllables from the scientific chemical name, in such a way as to indicate the significant groupings of the compound.
3. Names should, in general, not exceed four syllables.
4. Names should be distinctive in sound and spelling, and should not be liable to confusion with names already in use.
5. Names which are difficult to pronounce or to remember should be avoided.
6. The addition of a terminal capital letter or number should be avoided.

The seventh and eighth points are slightly different and are as follows for each organization:

World Health Organization:

7. Names already used in the national pharmacopoeias or officially adopted in any country, or which are included in New and Nonofficial Remedies, should receive preferential consideration.
8. The following terminations should be used:

Latin	English	
--inum	--ine	for alkaloids and organic bases

. . .

British Pharmacopoeia

7. Names used in the United States Pharmacopoeia, The British Pharmaceutical Codex, or New and Nonofficial Remedies should receive preferential consideration.
8. The following terminations should be used:

--ine (Latin --ina) for alkaloids and organic bases.

..."(1)

The American Medical Association's Council on Drugs is also working in co-operation with the World Health Organization. As stated in an editorial of the Association's Journal:

"The guiding principles used by the Council in selecting nonproprietary names may be stated quite briefly as follows: (1) The names must not conflict with established nonproprietary names and trademarks. (2) The names should indicate relationship to comparable known drugs. (3) The names should be short, euphonious, and easy to spell and remember. Sometimes it is not possible to achieve the latter 2 goals to an equal degree.

In the course of its negotiations the Council co-operates with the United States Pharmacopoeia, the National Formulary, the World Health Organization, the British Pharmacopoeia Commission, the French Codex, and the Nordic Pharmacopoeia in an attempt to choose names that may become available as international nonproprietary names."(2)

(1) Kalbfleisch, op. cit., pp. 12-16 at pp. 12-13.

(2) "New Names", The Journal of the American Medical Association, Vol. 178, No. 7, November 18, 1961, p. 162.

In the article previously referred to, Mr. Kalbfleisch describes as follows the safeguards which are exercised in Canada to keep confusion in pharmaceutical nomenclature to a minimum:

- "1. When a manufacturer presents a new drug submission for consideration by the Department of National Health and Welfare, he is asked to supply a proper name for the product. If the product is such that there is no existing proper name the Department may apply to the World Health Organization for an international non-proprietary name or the manufacturer may be advised to do so. In the process of assigning an international non-proprietary name, the Subcommittee on Non-Proprietary Names of the Expert Committee on the International Pharmacopoeia of the World Health Organization, which consists of a number of experts, consider the name submitted by the manufacturer according to principles laid down, and also check with other pharmacopoeial bodies to avoid conflict as much as possible.
2. Names for drugs which are issued in advance of pharmacopoeial status by the British Pharmacopoeia Commission, the Council on Pharmacy and Chemistry, and the World Health Organization, are given a measure of trade-mark protection in Canada since the Food and Drug Divisions of the Department of National Health and Welfare are usually consulted by the Trade Marks Branch of the Secretary of State Department regarding new trade-marks for pharmaceutical products.
3. The Canadian Committee on Pharmacopoeial Standards^[1] appoints subcommittees to advise the British Pharmacopoeia Commission on various subjects. One of these subcommittees deals with nomenclature and Mr. W.T. Thorne represents Canadian pharmacy very ably on this subcommittee.

[1] Now called the Canadian Drug Advisory Committee. See P.C. 1958-30 (June 12) and P.C. 1961-57 (January 19).

4. Appendix III^[1] of the Food and Drug Regulations may be employed whenever the need is apparent. This Appendix has been kept as small as possible in the belief that its value could be greatly reduced by adding to it without serious consideration."

Earlier in the same article, Mr. Kalbfleisch had written:

"... there is still a place for Appendix III for cases of duplication of official names, for the establishment of proper names where there is interference with trade-mark names in Canada, for the publicizing of proper names for new drugs, or for drugs which are known under a number of common or trade names."(2)

3. The Common Name

Until a proper name is established(3), a drug is designated by its common name, i.e. the name in English or French by which it is commonly known(4).

In exceptional cases, the chemical name of a drug may be used suitably as a common or proper name. To quote again from the article by Mr. P.G. Stecher:

"... Chemical names are used as generic names where they are sufficiently simple and do not contain numbers or symbols. Such is the case with most inorganic and a few organic drugs, and nobody will want to simplify such names as sodium bromide, sodium perborate, hydrogen peroxide, or glycerin. Most organic substances, however, require a generic name. It is one of the rules of prescription writing that no number or symbol shall be appended to a drug name unless it denotes dosage or quantity. This rules out most systematic chemical names of organic drugs."(5)

[1] Since the publication of the article, Appendix III has been replaced in the Food and Drug Regulations by the Table appearing under C.01.002.

(2) Kalbfleisch, op. cit., pp. 12-16 at p. 13.

(3) Appendix C to this Report, Food and Drug Regulations, C.01.004

(4) Appendix C to this Report, Food and Drug Regulations, C.01.001 (b)

(5) Stecher, op. cit., pp. 454-55.

Moreover, even if the chemical name of a drug is unwieldy, it may be used temporarily as its common name until a more appropriate one is agreed upon. It may also occur that, for an indefinite period, a new drug is commonly designated by the name suggested by the manufacturer as the proper name. If the suggested name possesses all the desirable attributes, there is no need to give it official status so long as it is commonly used. For this reason, one should not think that the work of the Food and Drug Directorate with respect to pharmaceutical nomenclature is confined to the drugs for which proper names have been established. Indeed, if after a certain time, there is technically no proper name, it is usually because the Directorate is satisfied with the common name and this may well be the result of close co-operation between the drug industry, the professional associations and the Department of National Health. In this respect, one should keep in mind that, as stated by The Canadian Pharmaceutical Association, Inc. in its submission to the Commission,

" . . . One of the chief purposes of the non-proprietary name is to provide a name common to all producers of the drug for the purpose of identification and by which it can be designated in the scientific literature of the various countries."

(Association brief, p. 38; Hearing, p. 2377)

Finally it should be noted that, under the Food and Drug Regulations (C.01.004; see Appendix C to this Report), the label of a single drug shall carry its proper or common name in type of not less than one-half the size of the brand name, if any, and immediately precede or follow the latter. In case of a mixture, the common or proper name of each ingredient must also appear unless reference is given to a standard or to a Canadian licence number.

In this report, the meaning of "proper names" has been broadened in compliance with common parlance to include the common names whose use over a long period of time seems to guarantee their acceptance by the Directorate as eventual proper names.

4. The Brand Name

Very often drugs are marketed under brand names which are usually registered as trade marks under the Trade Marks Act. The purpose of such a practice is to distinguish a particular firm's preparation of a given drug from those of other firms, or, in a case where there is no other manufacturer, to identify the particular

product with the sole manufacturer. For this reason, a trade mark becomes invalid, if it loses its distinctive character(1). To the extent that the existence of a proper name helps to prevent a brand name from being used as a common name, the proper name is useful for the conservation of the trade mark. Like the other types of name, brand names may not be misdescriptive(2). Contrary to the others, they are not descriptive either. For, under the law, a trade mark is not registrable, if it is "clearly descriptive. . . of the character or quality of the wares or services in association with which it is used or proposed to be used or of the conditions of or the persons employed in their production or of their place of origin. . ."(3).

The advantages of brand names were described as follows to the Commission:

(1) in the brief presented on behalf of Cyanamid of Canada Limited by Mr. R.B. Thompson, Manager of its Medical Products Department:

" . . . The brand name has grown up partly as convenience, due to the length and cumbersomeness of generic names, which are difficult to remember and to read on a doctor's prescription. It also serves as a means for distinguishing the company's product."

(Cyanamid brief, p. 27; Hearing, p. 1501)

(2) in the brief submitted on behalf of The Canadian Pharmaceutical Association by its General Manager and Secretary-Treasurer, Mr. J.C. Turnbull:

" . . . brand names and brand-named products undoubtedly have certain advantages, including (1) relatively easy to remember, (2) relative quality is known, (3) usually associate name with a company, (4) recall to mind distinctive physical properties, and (5) use assures that exactly the same product is supplied to his patients or to the same patient at different times. . . ."

(Association brief p. 41; Hearing, p. 2401)

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- (1) Harold G. Fox, The Canadian Law of Trade Marks and Unfair Competition, 2nd Edition, 1956, Vol. 1, pp. 430-434.
 - (2) Appendix B to this Report, Food and Drugs Act, s. 9(1); Appendix D to this Report, Trade Marks Act, s. 12(1)(b).
 - (3) Appendix D to this Report, Trade Marks Act, s. 12(1)(b).

Moreover it must be kept in mind that the range of drugs which may be designated by brand names is wider than that designated by proper and common names. To use the words of Dr. Lloyd C. Miller:

"It must be pointed out that nonproprietary names are considered only for single compounds, whether of synthetic or natural origin. While trademarks can be assigned to mixtures, only the active ingredients of such mixtures are designated by nonproprietary names."(1)

In this respect, the utility of brand names has been stressed as follows by Associate Professor J.L. Summers:

"PROF. SUMMERS: Let us take a drug combination which contains a number of individual items, let us say 8 items. This is much more easily described by a single brand name than having to list each of the 8 individual items, and therefore in this respect a trade name does have a useful purpose in the hospital."

(Hearing, p. 2289)

As pointed out by the Director (Green Book, p. 23), no distinction is made, in ordinary usage in the drug industry, between a brand name and a trade name. However, it seems incorrect and misleading to speak of the trade name of a particular drug, for, under the Trade Marks Act "'trade name' means the name under which any business is carried on. . ."(2). For this reason, the term "brand name" will be used in this report.

5. Use of Proper or Brand Names in Teaching

With respect to the use of proper or proprietary names in teaching, the Commission received the following evidence from:

(a) Dr. F.B. Rodman, Assistant Clinical Professor of Therapeutics at the University of Alberta:

(1) Miller, op. cit., p. 29.

(2) Appendix D to this Report, Trade Marks Act, s. 2 (v).

"MR. MacLEOD: Incidentally, in instructing your pupils, the prospective medical graduates, do you teach drugs by generic name or trade names?

DR. RODMAN: Oh, no, by the generic name, and the trade name is merely given for purposes of identification. We are stressing the use of the generic names, the metric system, and the metric dosage to our students, and also the question of cost has a part of every drug discussion that I make."

(Hearing, p. 907)

(b) J.L. Summers, Associate Professor of Pharmacy at the University of Saskatchewan:

"MR. MacLEOD: In your work do you teach either medical students or pharmacists?

PROF. SUMMERS: Yes, sir.

MR. MacLEOD: What do you teach in the way of names? Do you suggest the generic name, trade name or what?

PROF SUMMERS: This is a good question. It is very difficult to teach names. As well as medical students and pharmacists I teach to a group of nurses. These are the people who actually use, administer the drugs to the patient, therefore you must teach the non-proprietary names and the trade names and make sure they know the name that is currently used in the hospital by the medical staff.

MR. MacLEOD: That name would be generic?

PROF SUMMERS: It may be. It may not be. There is the drug pethidine which is sold under the name of demerol and another trade name, also meperidine. We use the brand Demerol therefore we must make sure our people remember the name Demerol.

MR. MacLEOD: What is Demerol?

PROF. SUMMERS: Pethidine Hydrochloride and Meperidine. It is an analgesic.

MR. MacLEOD: The first name is the brand name?

PROF. SUMMERS: Demerol is Winthrop's brand of pethidine hydrochloride.

. . .

MR. MacLEOD: In your teaching you would point out there is Brand A, Brand B, Brand C, Brand D.

PROF. SUMMERS: Absolutely. For example, tetracycline hydrochloride, we would say there are a number of brand names and we would have to use a cross-reference with all the available brand names. That we would do."

(Hearing, pp. 2283-86)

CHAPTER III

CLASSIFICATION OF DRUGS

1. Definition of Drugs

In the Food and Drugs Act [s. 2(f)], "drug" is defined as including:

"any substance or mixture of substances manufactured, sold or represented for use in

- (i) the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical state, or the symptoms thereof, in man or animal,
- (ii) restoring, correcting or modifying organic functions in man or animal, or
- (iii) disinfection in premises in which food is manufactured, prepared or kept, or for the control of vermin in such premises;"

From this definition, it appears that drugs may consist of bulk chemicals or organic substances such as extracts of plant or animal origin as well as manufactured pharmaceutical preparations of natural or synthetic derivation.

2. Official versus Non-Official Drugs

Drugs are either official or non-official. According to the Food and Drug Regulations,

"'official drug' means any drug

- (i) for which a standard is provided in these Regulations, or

- (ii) for which no standard is provided in these Regulations but for which a standard is provided in any of the publications mentioned in SCHEDULE B to the Act, "(1)

All other drugs are non-official. The importance of a standard for a drug is indicated by the fact that it must be complied with under the law.(2)

The official compendia are Pharmacopoea Internationalis, The British Pharmacopoeia, The Pharmacopoeia of the United States of America, Codex Français, The Canadian Formulary, The British Pharmaceutical Codex and The National Formulary.

In a letter dated November 26th, 1962, Mr. Grant L. Kalbfleisch, Secretary of the Canadian Drug Advisory Committee, conveyed to the Commission the following information with respect to the dates of the revisions and supplements of these compendia and about the length of time it takes for a new drug to find its way into one of them:

"... the U.S.P. is completely revised at five-year intervals, with supplements being issued as required. The fifteenth revision of the U.S.P. appeared in 1955 and the sixteenth appeared in 1960. The first supplement to the sixteenth revision appeared on May 1st, 1962.

... the Canadian Formulary was issued in 1949 and has never been revised. The Codex Français had its seventh revision in 1949 and is to be revised every twelve years with supplements every three years. A new edition of the Codex Français has not appeared, to my knowledge. The Pharmacopoea Internationalis is still in its first edition with Volume I having appeared in 1951, Volume 2 in 1955 and a supplement in 1959. I believe the second edition is due in 1963.

... With reference to the B.P., there have been complete revisions in 1948, 1953 and 1958 with an addendum between each edition. These are published two years after the pharmacopoeia. The British Pharmaceutical Codex is also published on a five-year basis, with supplements being issued three years after the date of the edition.

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- (1) Appendix C to this Report, Food and Drug Regulations, C.01.001 (e)
 - (2) Appendix B to this Report, Food and Drugs Act, s. 10.

A supplement to the B.P.C. is expected in December. The National Formulary is issued on a five-year review cycle also but to my knowledge there are no supplements.

. . . If you tabulate the dates of the revisions and supplements of these books, you will see that drug standards are under constant review.

It is impossible to guess how long it takes any drug to become official in these compendia because this depends on the acceptance of each individual drug by the Board of Revision in each case. Some drugs have been accepted very quickly because there was a need for them and there was no alternative treatment. Many drugs, on the other hand, are never accepted because the Revision Committee may not regard them as an advance in therapeutics over what is already in the pharmacopoeias."

According to J.L. Summers, Associate Professor of Pharmacy at the University of Saskatchewan, and Mr. J.C. Turnbull, General Manager and Secretary-Treasurer of The Canadian Pharmaceutical Association, Inc., the great majority of the official drugs contain only one active ingredient, but a few of them are compounded mixtures (Hearing, pp. 2265-66 and 2404).

3. Proprietary versus Ethical Drugs

The terms "proprietary medicine" or "patent medicine" are synonymous. Strictly speaking, they refer to a medicament registered under the Proprietary or Patent Medicine Act. Curiously enough such a medicament is not patented. As a matter of fact no medicinal formula is now patentable under the Canadian law.⁽¹⁾ However, when Parliament first enacted the Proprietary or Patent Medicine Act in 1909, it was possible to patent a medicinal formula and this Act was then the only federal statute concerned with the control of proprietary or patent medicines. This is the historical explanation for the present use of such ambiguous terminology.

The purpose of the Proprietary or Patent Medicine Act is to make possible safe self-medication. With respect to this matter, Dr. C.A. Morrell, Director of the Food and Drug Directorate of the Department of National Health and Welfare, has stated:

(1) Appendix E to this Report, Patent Act, s. 41(1).

"If the Proprietary or Patent Medicine Act were removed from our legislative authority some other means would have to be produced to provide safe and honest household remedies that can be purchased in other premises than those under the charge of a pharmacist. There are in nearly every province large areas where a pharmacist does not operate and indeed where he might find it difficult to make a living, but which nevertheless are inhabited by a considerable number of people having casual illnesses like the rest of us for which they want a 'remedy'. It is this need that must somehow be provided for and some competent authority must be there to make certain that the products sold are neither harmful or fraudulently represented."(1)

In accordance with this objective, no medicine is registered under the Act, if it contains a narcotic(2), an excess of alcohol(3) or a new drug (Hearing, pp. 107-10) or if it is restricted to prescription sale(4) or intended for use as a treatment for certain diseases for which medical advice should be sought(5). Moreover, the medicinal formula should not appear either on the label or in any of the official pharmacopoeias or formularies(6). Because of this, it is said to be secret, but it must be disclosed to the Chief of the Proprietary or Patent Medicine Division. While no false, misleading or exaggerated claims may be made(7), advertising is allowed and, as a matter of fact,

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- (1) Dr. C.A. Morrell, "Government Control of Food and Drugs", Canadian Pharmaceutical Journal, Vol. 90, No. 6, June, 1957, p. 343.
 - (2) Appendix F to this Report, Proprietary or Patent Medicine Act, s. 7 and 8(1)(a).
 - (3) Appendix F to this Report, Proprietary or Patent Medicine Act, s. 8(1)(b).
 - (4) Appendix B to this Report, Food and Drugs Act, Schedule F; Appendix C to this Report, Food and Drug Regulations, C.01.041.
 - (5) Appendix B to this Report, Food and Drugs Act, s. 3.
 - (6) Appendix F to this Report, Proprietary or Patent Medicine Act, s. 2(1)(d).
 - (7) Appendix F to this Report Proprietary or Patent Medicine Act, s. 8(1)(e) and (f); Appendix B to this Report Food and Drugs Act, s. 9.

carried out rather extensively. Finally the legislation of all Canadian provinces⁽¹⁾ except, since 1962, Nova Scotia⁽²⁾ permits stores other than drug stores to sell such drugs. In his evidence before the Commission, Dr. Morrell stated that the number of registered medicines is somewhere between 3,000 and 3,200 (Hearing, pp. 113-14).

However, the term "proprietary drug" is not always used in this strict sense. Speaking broadly, it means any common drug which is advertised to the public and usually bought without prescription. Thus it includes acetylsalicylic acid, commonly sold under such brand names as Aspirin, Acetophen and Salotyn. Such a drug, however, cannot be registered, because its formula appears in one of the official pharmacopoeias or formularies. In this report the term "proprietary drug" is used in its broad sense, while the term "registered medicines" designates only those registered.

In the laws of every province except New Brunswick and Prince Edward Island, proprietary drugs other than registered medicines, fall under a general prohibition making it illegal for anyone other than a registered pharmaceutical chemist to sell them. To this general prohibition there are exceptions. Moreover in certain provinces, some excepted drugs may be sold by other persons than a pharmaceutical chemist only in areas within a specified distance of which no registered pharmaceutical chemist is carrying on business. In each of the provinces of New Brunswick and Prince Edward Island, the Pharmacy Act⁽³⁾ lists the drugs which may be sold only by registered pharmacists. It is of interest that the same drug does not receive the same treatment in all provinces. For instance, in Prince Edward Island, acetylsalicylic acid may be sold only by a registered pharmacist; this is also true in Quebec⁽⁴⁾, except in areas where there is no pharmacy within a radius of five miles; on the contrary, in Ontario, it may be sold in any kind of establishment⁽⁵⁾.

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- (1) Revised Statutes of British Columbia, 1960, c. 282, s. 46; Revised Statutes of Alberta, 1955, c. 232, s. 31(1); Statutes of Saskatchewan, 1954, c. 74, s. 42(1)(a) and (48); Statutes of Manitoba, 1961, c. 46, s. 20; Revised Statutes of Ontario, 1960, c. 295, s. 2(b); Revised Statutes of the Province of Quebec, 1941, c. 267, s. 31; The New Brunswick Pharmaceutical Act, 1958, s. 34; Revised Statutes of Prince Edward Island, 1951, c. 110, s. 24(3); Statutes of Newfoundland, 1954, No. 51, s. 29(2)(a).
 - (2) Statutes of Nova Scotia, 1962, c. 11.
 - (3) Revised Statutes of Prince Edward Island, 1951, c. 110, s. 24(1); The New Brunswick Pharmaceutical Act, 1958, s. 27.
 - (4) Statutes of Quebec, 1952-53, c. 55, s. 30.
 - (5) Revised Statutes of Ontario, 1960, c. 295, s. 2(k).

In common usage, the second main category of drugs is designated by the words "ethical drugs". When used in a strict sense, these words refer to prescription drugs, that is to say drugs which may legally be sold only on prescription. In the statutes of certain provinces, there are provisions restricting specified drugs on prescription sales⁽¹⁾. Moreover, under the Food and Drug Regulations, "No person shall sell a drug listed or described in Schedule F to the Act . . . unless he has received a prescription therefor, . . ."⁽²⁾.

In his evidence, Dr. Morrell said that he is chairman of a committee consisting of himself, and one representative of the Canadian Medical Association and one representative of The Canadian Pharmaceutical Association, which committee makes recommendations to the Minister of National Health and Welfare as to which drugs should be sold only by prescription. Dr. Morrell went on to say that the main consideration which entered into a decision to put a drug on the prescription list is whether it has been abused or is likely to be abused or misused. It is not necessarily the toxicity per se, as all drugs have a danger in that respect. Some drugs are on the list because of toxicity per se, but most of them are not. Barbiturates and tranquilizers have been put on the list because of misuse and abuse. Even the antibiotics have been included for the same reason. Another consideration leading to the placing of a drug on the prescription list is that it is likely to be used or is used for treatment of a disease for which it was intended but that if used constantly and over a long period of time might produce undesirable side reactions. Such a situation might arise if a patient was taking the drug himself without a doctor's supervision. When asked what factors led to a large number of tranquillizers being added to the prescription list in 1959, Dr. Morrell replied that some tranquillizers had been so listed earlier and he thought that about 1958 the Committee on Pharmacy of the Canadian Medical Association recommended to the Department that all so-called tranquillizers as well as hypnotics and sedatives be put on prescription. After a considerable period of discussion the recommendation was adopted (Hearing, pp. 131-33).

Unlike proprietary medicines, prescription drugs are usually promoted to prescribing doctors and dispensing pharmacists only. Clearly there is no inducement to advertise to the general public a drug that may legally be sold only on a prescription. Moreover, such a practice is prohibited by the Regulations for Schedule F drugs⁽³⁾. However, because in critical

(1) For example, Revised Statutes of Ontario, 1960, c. 295, s. 45, 46.

(2) Appendix C to this Report, Food and Drug Regulations, C.01.041.

(3) Appendix C to this Report, Food and Drug Regulations, C.01.044.

circumstances self-medication should be discouraged, there are restrictions on advertising with respect to two other categories of drugs which may legally be sold without a prescription. Firstly, there is a statutory prohibition of advertising drugs as treatments or cures for the diseases listed in Schedule A of the Food and Drugs Act.(1) In regard to this matter, the following evidence was given by Mr. Alfred Pepper, President of The Saskatchewan Pharmaceutical Association:

"MR. MacLEOD: What about that class of product? Is there price cutting on those, in your experience?

MR. PEPPER: Very little because so little is known about them. They are not advertised to the public usually and there doesn't seem to be much point in advertising a cut price on a commodity that is not known to the public.

MR. MacLEOD: You would be allowed to advertise the price of such a product, would you not?

MR. PEPPER: Yes.

MR. MacLEOD: Although you could not advertise it as being a remedy for stomach ulcers or something like that?

MR. PEPPER: There is nothing that would stop you advertising the price."

(Hearing, pp. 819-20)

Secondly, the Food and Drug Regulations(2) prohibit the advertising to the general public for human use of a number of listed drugs when the recommended single or daily dose exceeds some specified limit. Because of these restrictions on advertising, promotion is directed to doctors and pharmacists with the ensuing result that the two categories of drugs referred to above are generally sold on prescription, even if a prescription is not legally required.

(1) Appendix B to this Report, Food and Drugs Act, s. 3(1).

(2) Appendix C to this Report, Food and Drug Regulations, C.01.021 and C.01.027.

Moreover, irrespective of any legal provision, some manufacturers may choose to promote some drugs as though they required a prescription. This would seem to be the case with respect to vitamin and iron compounds and also gastric remedies according to the evidence given before the Commission by Dr. Nathan Schechter, Chairman of the Pharmacy Committee of the Ottawa Civic Hospital:

"DR. SCHECTER: Yes, in the case of vitamin compounds, iron compounds, and various stomach gastric remedies no prescription strictly speaking is necessary, but some of the so-called ethical pharmaceutical companies will not allow a patient to buy over the counter, and prescriptions are necessary in those cases.

I don't really know just what the situation would be if a patient were given the name of some of these vitamins or iron preparations and told to go to the drug store and ask the pharmacist for it. I don't know what the reaction would be."

(Hearing, pp. 245-46)

"MR. FRAWLEY: There is only one other thing that I wanted to ask. You told Mr. MacLeod that there are certain drugs that could be, if the patient knows the name of it, he should be able to buy without a prescription because there is no requirement by law that it must only be dispensed on prescription, but you said something which swept me [sic], that if he went in a drug store and asked for it without a prescription, you didn't quite know what the reaction would be to supplying him. Was that on the part of the druggist or the manufacturer?

DR. SCHECTER: On the part of the druggist. As I say, some of the companies tell us that they don't allow their drugs to be sold over the counter. Mr. MacLeod asked if all drugs required prescriptions, and I said that there are some, vitamins and iron compounds, anti acid, [that] don't require prescriptions, but some of the companies will not allow their drugs to be sold over the counter without prescription."

(Hearing, pp. 280-81)

With respect to any such practice as that described above, the following evidence was received by the Commission from the following sources:

(a) from Dr. J.W. Reid, a practising physician in the City of Halifax:

"THE CHAIRMAN: I was going to ask one further question about your comment concerning drugs which the law does not require to be sold on prescription only but which you find it necessary to prescribe for in order that patients will secure them. Why is it necessary to prescribe for drugs which the law does not require to be prescribed for?

DR. REID: It is largely because I may want that patient to have a combination of drugs. For instance, I may want that patient to have simple aspirin but I may want with it some tablet or some other chemical to aid in the treatment of that patient, so I would have to prescribe that.

THE CHAIRMAN: I understand that kind of case, but I was wondering if there are cases, many or few, in which the manufacturer instructs the druggist that they should be sold only on prescription.

DR. REID: I don't know of that.

THE CHAIRMAN: You don't know of any?

DR. REID: No.

THE CHAIRMAN: We heard some evidence to that effect last week and I was wondering if it was fairly common?

DR. REID: Actually the medical profession does not want to use in its professional prescriptions drugs which the patient can go and buy as a chemical. For one thing, if it can be purchased over the counter, it is not likely to be a very potent thing and we would not be asked to prescribe it.

There are exceptions to that, aspirins and a few other preparations of that kind are available for treatment whether purchased by patients or whether prescribed by the doctor, but there are not too many. Most of the things sold over the counter are by genuine Companies, the sort of thing a patient can purchase. We prescribe largely

because -- we are prescribing not single drugs in that way, but combinations."

(Hearing, pp. 395-97)

(b) from Mr. Walter Maday, President of The Alberta Pharmaceutical Association:

"MR. FRAWLEY: What Dr. Schechter is saying though, is that some of those drugs not in Schedule F, not limited to dispensing by prescription, that for some reason you cannot buy those over the counter and must present a prescription, and that comes from the manufacturer. Do you know of that?

MR. MADAY: No I don't. I think it is the pharmacist's professional knowledge that prohibits the sale of certain items. I refer back to some of these non-barbiturate analogues for inducing sleep. They were not on the schedule. I can say that well in the 90 to 95% of the pharmacists never sold them. They felt they were unsafe.

THE CHAIRMAN: Except with a prescription?

MR. MADAY: That is right. In other words, the individual patient should not and did not have the right to ask for it.

. . .

THE CHAIRMAN: What do the druggists in Alberta do with regard to these specific drugs that Mr. Frawley has been asking about? Do you sell them over the counter, or only on prescription?

MR. MADAY: The majority only on prescription.

THE CHAIRMAN: That is entirely a matter of the individual pharmacist's own decision?

MR. MADAY: Of his professional decision, yes."

(Hearing, pp. 1041-43)

(c) from Mr. J.W. Richardson, Vice-President of The Manitoba Pharmaceutical Association:

"THE CHAIRMAN: In your experience do manufacturing companies request that you do not sell certain products except under prescription. Even though you may not comply with the request, do you get that sort of request from manufacturers?

MR. RICHARDSON: No sir, I have never received that request personally.

MR. MacLEOD: Are prescriptions sometimes written for drugs and medicinals for which a prescription is not legally required?

MR. RICHARDSON: Yes sir.

MR. MacLEOD: Would that be true of most drugs and medicinals, except patent medicines? In other words, in your experience would you find that virtually every type of drug, except the patent medicines, would be prescribed at one time or another?

MR. RICHARDSON: Well, other than patent medicines they have been prescribed at one time or another, but not necessarily sold today. By that I mean as the public learns about things and often today the doctor will suggest to the patient that he go and buy a certain thing, we are receiving more requests by the public for some of these products that are not patented expressly."

(Hearing, p. 660)

(d) from Mr. S.N. Conder, General Manager of the Canadian Pharmaceutical Manufacturers Association:

"In respect to marketing, one witness before this Commission referred to companies insisting that non-prescription products be sold only on prescription. This point subsequently has arisen many times during the Commission's cross-examination of witnesses. Accordingly, we asked our companies this question: 'Have you at any time insisted that non-prescription items be sold only on prescription at the retail level?' The 39 companies which replied to this survey all stated 'no'.

One company qualified its negative reply, by first stating that it has never insisted that this be done, but adding that it may have dissuaded a retail pharmacist from selling a non-prescription product over the counter:

'As an example, if we were asked by a retail pharmacist if one of our antihypertensive agents could be sold over-the-counter, our answer would be that it could be sold legally. But since it is a potent substance which is used in the treatment of a serious ailment, we would suggest that in the patient's interest, it would be preferable that a physician be consulted'.

Another company followed this example in 1956 during introduction of a new and highly potent ataractic of the perphenazine family. In view of extrapyramidal symptoms involved in this drug, the dosage had to be carefully adjusted to the patient according to recommended maximums. This company felt that the drug should be used only under a physician's supervision, but ataractics were not officially classified as prescription drugs at that time. For this reason, the company discouraged over-the-counter sale of this product until it and other ataractics were eventually placed on the prescription list.

The final decision was, of course, left to the pharmacist's discretion, and it is generally accepted that our companies do not and can not insist that non-prescription items be sold on prescription."

(Association brief, pp. 15-16; Hearing, pp. 1827-28)

From the above evidence, it appears that none of the four witnesses was aware of the practice described by Dr. Schechter. However it should be noted that, according to Dr. Reid, physicians are somewhat reluctant to prescribe over-the-counter drugs. According to Mr. Maday, pharmacists, as a matter of professional decision, sometimes require a prescription for drugs they are allowed to sell over the counter. Finally 37 of the 39 member companies which answered to a survey conducted by the Canadian Pharmaceutical Manufacturers Association⁽¹⁾ denied having insisted that non-prescription items be sold only on prescription; as to the other two, they had recommended such a course of action, but in each case the final decision had been left to the pharmacist's discretion.

(1) In this Report this Association is sometimes referred to as C. Ph. M. A.

There are other reasons why physicians give a prescription for a drug which may be bought over the counter. For instance a patient may well require such a prescription for purposes of income tax deduction⁽¹⁾ or in order to be reimbursed under a comprehensive health insurance scheme⁽²⁾. Moreover it appears, from the following excerpt from the evidence of Dr. J.P. Gemmell, Associate Professor, Faculty of Medicine of the University of Manitoba, that a physician may find it desirable to give such a prescription to a patient for psychological reasons:

"MR. MacLEOD: In discussion with the Chairman a few moments ago you pointed out that the public demands drugs. Is this reflected in the writing of a prescription for drugs for which no prescription is legally required? I may expand on that. Is it sometimes desirable in order to satisfy a patient and make them perhaps believe more in the drug to give them a prescription for a drug rather than tell them to run down to the drug store and get so-and-so?

DR. GEMMELL: If you mean do I write a prescription for acetylsalicylic acid and they take it instead of going down to, say, Eaton's and get 500 for \$1.98, yes. I must confess I have written prescriptions for this, and sometimes for very specific reasons.

THE CHAIRMAN: Sometimes the psychological effect on the patient would make you do it, I suppose?

DR. GEMMELL: Well, I think the figure is as high as 25% of the population, perhaps closer to 50% of the population, are called placebo reactors, . . . - I would advise you not to even smile at this, because this is a tremendously important therapeutic thing, this presents terrible problems. . . . It is a terrible problem to doctors when you are evaluating new drugs, when you know that 25% of the people are going to get better no matter what you do for them.

(1) Income Tax Act, s. 27(1)(c)(viic).

(2) For instance, under the Surgical-Medical Insurance Plan for employees in the Public Service of Canada, drugs and medicines are eligible expenses only if prescribed by a physician or surgeon and dispensed by a licensed pharmacist.

THE CHAIRMAN: If you give them a sugar-coated pill.

DR. GEMMELL: The fancier it is the better its effect. We tend to associate red drugs for building blood. There is a great amount of the primitive in us yet, you know?

THE CHAIRMAN: Doctors have to know that in order to prescribe effectively.

DR. GEMMELL: I think you know that instinctively."

(Hearing, pp. 534-35)

Moreover, according to a study prepared by the Pharmacy Committee of the British Columbia Division of the Canadian Medical Association⁽¹⁾, the average Canadian diet provides a gross excess of vitamins and the overwhelming majority of prescribed vitamins almost certainly are given for placebo reasons.

Drugs for which no prescription is required by law, but which are in fact usually sold on prescription are sometimes called over-the-counter ethical drugs. Thus the term "ethical" applies to all drugs that are not advertised to the public and which are generally sold by pharmacists⁽²⁾ on prescription. As to the ethical drugs for which a prescription is required by the law, they will be referred to as "prescription drugs" throughout this report.

On the respective proportions of ethical drugs which are either prescription or over-the-counter drugs, the following information was given in his evidence by Mr. K. Antoft, President of Nordic Biochemicals Ltd., an ethical drug manufacturing firm:

"MR. MacLEOD: Just to clear up one point which arises out of Mr. Frawley's questions. You said some of your products must be sold on prescription and some don't require prescriptions. Do you regard that second class of drugs as ethical drugs?

(1) "The Cost of Vitamin Therapy", a study prepared by the Pharmacy Committee of the British Columbia Division of the Canadian Medical Association, British Columbia Medical Journal, Vol. 3, No. 12, December 1961, pp. 655-56. See Appendix N to this Report.

(2) For example, see Revised Statutes of Ontario, 1960, c. 295, s. 38; Statutes of Quebec, 1952-53, c. 55, s. 21.

MR. ANTOFT: Yes, because none of our products are advertised directly to the public. The Canadian Food and Drug Regulations has only a very limited list of drugs that require a prescription. These are the ones that are subject to obvious abuse. For example some years ago the Canadian Food and Drug Administration removed without any prior notice to us, which, of course, didn't matter one way or the other, but we were surprised when ACTH was removed from the prescription list or removed from Schedule F of the Act. When I inquired for the possible reason for this there was a very logical explanation. We were trying to simplify the administration of the Act. We thought it was highly unlikely a patient would administer ACTH unless he was under the care and supervision of a physician so therefore this is an unnecessary encumbrance on the administration and not a drug which is subject to abuse.

MR. MacLEOD: Is there a considerable number of drugs that while they are not prescription drugs are nevertheless considered by the industry and by the profession to be ethical drugs?

MR. ANTOFT: Very definitely. The majority, I would say that the majority of drugs manufactured by ethical drug manufacturers are not Schedule F drugs, and therefore may be bought on an over-the-counter basis."

(Hearing, pp. 1424-25)

4. Brand-Named versus Generic Drugs

In common parlance, brand-named are opposed to generic drugs. However it follows from what has been said about pharmaceutical nomenclature that scientifically there is no such thing as a generic drug. This is loose terminology to designate unbranded preparations marketed under the proper name assigned to a drug. In the same way, the expression "generic manufacturer" is used to designate a manufacturer specializing in the fabrication of generic drugs. Despite the fact that this terminology is not scientific, it will be resorted to in this report for the sake of convenience and brevity and also because it is used again and again in the excerpts of evidence hereinafter quoted. It should be noted however that meprobamate, by way of example, is one and the same tranquillizer, whether marketed as a generic under this non-proprietary name of meprobamate or under the brand names of Equanil, Miltown and so on.

CHAPTER IV

THE DRUG MANUFACTURING INDUSTRY

1. Number of Firms and Employees, and Value of Shipments

As shown below in Table 1, the value of factory shipments made by manufacturers of pharmaceuticals and medicines increased between 1955 and 1960 from \$108,121,734 to \$164,896,766, that is to say by over 52 per cent.

Table 1

Number of Establishments and Employees
and Selling Value of Factory Shipments,
Manufacturers of Pharmaceuticals and
Medicines, Selected Years 1939-60

Year	Number of Establishments	Number of Employees	Selling Value of Factory Shipments (\$)
1939 ¹	174	4,388	27,184,262
1945 ¹	204	8,329	60,330,928
1955 ¹	210	7,629	108,121,734
1957 ¹	207	8,146	140,092,919
1957 ²	202	7,945	135,968,896
1958 ²	193	7,838	150,027,056
1959 ²	184	7,974	159,048,927
1960 ²	198	7,994	164,896,766

¹Data for these years are on the basis of the Standard Industrial Classification in use prior to 1960.

²Data for these years are on the basis of the Standard Industrial Classification, revised, 1960.

Source: Dominion Bureau of Statistics, Manufacturers of
Pharmaceuticals and Medicines, 1960, Tables 1A
and 1B, pp. 5-6.

The nature of the data included in Table 1 and collected by the Dominion Bureau of Statistics has been described in part as follows:

"Factory shipments refer to shipments of goods made from own materials either in the reporting plant or by other manufacturers on the basis of a charge to the reporting plant for work done. All products and by-products shipped from the establishment are included whether for domestic use, export, or for government departments. Transfer shipments to sales outlets, distributing warehouses or to other manufacturing units of the reporting firm are included. Goods bought or received as transfers and resold without further processing are not included. Values are computed on f.o.b. plant or plant warehouse basis, and do not include sales tax or excise duties. Values of containers not returnable are included. Amounts received in payment for work done on materials owned by others are included.

. . .

. . . For statistical purposes the industry titled Manufacturers of Pharmaceuticals and Medicines in the revised Standard Industrial Classification covers the operations of establishments primarily engaged in manufacturing drugs and medicines. This industry includes manufacturers of patent and proprietary medicines; veterinary medicines; vitamin products; cod liver oil preparations; and biological products, such as antitoxins, bacterins, serums, vaccines; as well as establishments primarily engaged in manufacturing antibiotics. Establishments primarily engaged in grinding drugs and herbs are also included.

. . .

The establishments in this industry make pharmaceuticals and medicines as their main products, but some also manufacture other lines, such as toilet preparations, soft drink powders and flavouring extracts, as a secondary part of their business. On the other hand, some companies which have been classified to other industrial groups make some pharmaceutical and medicinal preparations as minor products. The total value of factory shipments of all pharmaceuticals and medicines (including amounts from other industries) was \$159,390,000 in 1960 as compared with \$154,334,000 in 1959."⁽¹⁾

(1) Dominion Bureau of Statistics, Manufacturers of Pharmaceuticals and Medicines, 1960, pp. 3-5.

As these data were collected on an establishment basis, whenever a company operated several factories, a separate report was made for each plant. However it should be noted that, in the Directory of Firms which is part of the report, Manufacturers of Pharmaceuticals and Medicines, 1960, (pp. 13-15) the Dominion Bureau of Statistics does not list the following firms which in 1961 were members of the Canadian Pharmaceutical Manufacturers Association:

Ames Company of Canada, Ltd.
Arlington-Funk Laboratories Division, U.S. Vitamin
Corporation of Canada, Ltd.
Beecham Research Laboratories Ltd.
Hoechst Pharmaceuticals of Canada Limited
Lakeside Laboratories (Canada) Limited
Mead Johnson & Co. of Canada Ltd.
G.D. Searle & Co. of Canada Limited
Winthrop Laboratories of Canada Ltd.

(Appendix B to the C.Ph.M.A. brief;
Green Book, pp. 263-84)

Figures for the value of sales of pharmaceutical preparations are also found in a publication of the Department of National Revenue entitled "Taxation Statistics". However, as appears from the following excerpt, the word "sales" is not given therein the same meaning as in the Dominion Bureau of Statistics reports:

"Sales (Item 28) . . . As far as possible, sales are taken gross, prior to deducting freight or transportation charges but after deducting discounts allowed, sales tax and sales rebates or refunds."⁽¹⁾

Moreover the pharmaceutical preparations industry, as defined for the purpose of Taxation Statistics, includes a much larger number of firms. In 1959, for example, the Dominion Bureau of Statistics classification includes either 188 establishments (old basis) or 184 establishments (new basis), while Taxation Statistics includes 245 or 247 firms in that year (1961 Taxation Statistics, pp. 104 and 127). As a result of different bases for number of firms and different methods of computing value of sales, 1961 Taxation Statistics shows a much higher value of sales. For 1959, the Dominion Bureau of Statistics report gives \$159,048,927 (new basis) as the selling value of factory shipments, while 1961 Taxation Statistics gives \$227,400,000 for value of sales in 1959.

(1) Department of National Revenue, 1961 Taxation Statistics, p. 96.

With reference to the total of 188 establishments (old basis) for 1959 published by the Dominion Bureau of Statistics, the brief presented by the Canadian Pharmaceutical Manufacturers Association stated:

"Many of these 188 firms are small regional concerns, while others manufacture proprietary preparations exclusively. It has been estimated, however, that about 70 of them are multi-line ethical pharmaceutical manufacturers, as we understand the term, about 75 are multi-line proprietary manufacturers, while the balance are agents, wholesalers and retailers who also manufacture some medicinals plus packaging concerns and other suppliers. Furthermore, this list does not include two major companies which manufacture ethical pharmaceuticals in Canada, and which are members of our Association."

(Association brief, p. 7; Hearing, p. 1811)

It should be noted that the Dominion Bureau of Statistics report cited refers to 188 establishments, which by definition are not synonymous with firms.

2. Location

The pharmaceutical manufacturing industry is located largely in the Central Provinces. In 1960, 177 establishments, or 89.4 per cent of the Canadian total, were located in Ontario and Quebec and 7,830 employees or 97.9 per cent of the Canadian total were employed by these establishments.

3. Products Manufactured

As shown in Table 2, approximately 92 per cent of the total value of all products shipped by the industry in 1960 consisted of medicines and pharmaceuticals. Of the total shipments of medicines and pharmaceuticals, 16.05 per cent consisted of proprietary or patent medicines. Antibiotics and preparations thereof, one of the categories of drug with which this report is particularly concerned, accounted for \$21,073,464 or 13.83 per cent of total medicines and pharmaceuticals.

There is undoubtedly some double-counting in Table 2. Fine Chemicals of Canada Ltd., for example, sells only bulk chemicals which are then used by other firms to make dosage forms, the value of which also appears in Table 2. Another clear example is seen in the item "Vitamins in bulk" and "Vitamin preparations in which the principal active ingredients are vitamins". For these reasons the totals are too large if considered to be measures of the outflow of finished dosage forms to various levels of the trade.

Of the total of \$186,762,000 representing Canadian production plus imports, the brief presented by the Canadian Pharmaceutical Manufacturers Association estimated that about 22 per cent represented proprietaries and the remainder was made up of ethical pharmaceuticals and biologicals for both human and veterinary use (Association brief, p. 7; Hearing, p. 1812).

Table 2

Manufacturers of Pharmaceuticals and Medicines
Breakdown of Factory Shipments by Type of Products
for 1959 and 1960

Product	Value of factory shipments	
	1959 \$	1960 \$
Medicines and pharmaceuticals:		
Registered as patent medicines and sold without all ingredients declared	24, 467, 133	24, 442, 717
Antibiotics and preparations:		
Penicillin preparations	4, 320, 538	4, 260, 360
Streptomycin preparations	349, 995	327, 744
Penicillin-streptomycin combinations	1, 030, 263	760, 331
Other antibiotics and preparations thereof ⁽¹⁾	15, 113, 098	15, 725, 029
Sex hormones	2, 806, 965	2, 663, 821
Sulphonamide (sulpha) preparations with or without other active ingredients	2, 541, 684	1, 603, 196
Vitamins and preparations:		
Vitamins in bulk	18, 331, 519	17, 211, 147
Vitamin preparations in which the principal active ingredients are vitamins	6, 120, 321	3, 940, 726
Biologicals and vaccines (excluding sex hormones)	1, 440, 519	1, 551, 536
Oral antiseptics	55, 331, 500	60, 635, 336
Ethical specialties for human use not elsewhere specified	10, 992, 715	10, 893, 859
All other human medicines	3, 518, 731	3, 782, 551
Veterinary medicines	-	4, 522, 152
Miscellaneous medicines and pharmaceuticals (including medicinal chemicals and feed supplements)	146, 364, 981	152, 320, 505
Total, medicines and pharmaceuticals	270, 167	318, 568
Disinfectants	441, 287	423, 794
Insecticides	390, 727	360, 307
Flavoured extracts	8, 237, 609	6, 603, 871
Toilet preparations ⁽³⁾	9, 028, 265	4, 869, 721
All other products ⁽⁴⁾	164, 733, 036	164, 896, 766
TOTALS		

(2)

(2)

(4)

- (1) Includes penicillin, streptomycin and other antibiotics as well as antibiotic preparations not elsewhere specified.
- (2) Included with "All other human medicines".
- (3) Includes soap, packaged goods, fountain supplies and syrup and other such articles.

(4) It will be noted that the 1959 figure of \$164,733,036 for total shipments differs from the figure of \$159,048,927 for the same year appearing in Table 1. This difference occurs because the data for 1959 in Table 1 are on the basis of the Standard Industrial Classification, revised, 1960, while the breakdown of factory shipments by products for 1959 is not available except on the basis in use prior to the 1960 revision.

NOTE: Data given in this table are for the Medicinal and Pharmaceutical Preparations Industry ONLY and represent only the production of the firms classified to this group.

Source: Dominion Bureau of Statistics, Manufacturers of Pharmaceuticals and Medicines, 1960, Table 3, p. 7;
The Medicinal and Pharmaceutical Preparations Industry, 1959, Table 3, p. 6.

4. Production, Imports and Exports

Domestic disappearance indicates the volume of drugs which enter into the various stages of manufacture and distribution, and which in these ways are retained in Canada from the pool made up of Canadian shipments plus imports. As shown in Table 3, imports in the years 1955 to 1960, inclusive, showed a small but steady decline as a percentage of domestic disappearance.

Table 3

Canadian Domestic Disappearance of Pharmaceuticals and Medicines, 1955-60

(\$000)

Year	Shipments	Imports	Exports	Domestic Disappearance ⁽¹⁾	Imports as per cent of Domestic Disappearance
1955	100,878	24,599	4,248	121,229	20.29
1956	110,002	26,121	5,349	130,774	19.97
1957	126,297	28,392	6,835	147,854	19.20
1958	139,621	29,238	9,560	159,299	18.35
1959	154,334 ⁽²⁾	32,428	6,758	180,004	18.02
1960	159,390 ⁽²⁾	32,613	5,726	186,277	17.51
1961	N.A.	40,972	9,029	-	-

(1) Canadian shipments plus imports minus exports.

(2) These figures are higher than those appearing in Table 2 for the same years. The discrepancies are accounted for by the fact that in Table 3 the shipments¹ figures represent total Canadian shipments, including some medicinals made in other industries as well as those made by firms classified by the Dominion Bureau of Statistics as manufacturers of pharmaceuticals and medicines.

Sources: Dominion Bureau of Statistics, Manufacturers of Pharmaceuticals and Medicines, 1960, Table 5, p. 9, and Trade of Canada, Imports; Trade of Canada, Exports, December 1961.

That imports in 1960 formed 17.5 per cent of domestic disappearance in 1960 is not to be interpreted to mean that imported drugs formed that percentage of all the dosage forms reaching the retail drug stores and the consumer, as the imports include not only some finished dosage forms but raw materials and semi-manufactured drugs which are further manufactured in Canada before passing into the inventories of wholesale and retail drug firms. The figures indicate an increase in domestic disappearance of 53.66 per cent from 1955 to 1960. Shipments of medicines and pharmaceuticals by all Canadian firms manufacturing such products, regardless of the industry into which they were classified, increased by 58.0 per cent.

The available import statistics do not permit an accurate analysis of the importance of imports to Canadian domestic disappearance for each class of drugs with which this report is particularly concerned. For the penicillins, streptomycins, other antibiotics and preparations of these drugs, however, it is possible to gain a general impression.

Table 4 deals with penicillins, streptomycins and combinations of them. The reason for dealing with these three classes of drugs together is the presence in the figures for Canadian shipments of the item "penicillin-streptomycin combinations". The alternative to lumping together penicillins, streptomycins and combinations of them is to attempt to separate them into the three separate classes, but this would be prevented by the absence of import and export categories for penicillin-streptomycin combinations.

Table 4

Canadian Domestic Disappearance
of Penicillins and Streptomycins,
as well as Preparations and Com-
binations Thereof, 1955-61

Year	Canadian Shipments*	Imports	Exports	Domestic Disappearance	Imports as per cent of Domestic Disappearance
	\$	\$	\$	\$	
1955	3,489,169	888,770	987,740	3,390,199	26.22
1956	4,168,801	1,081,545	375,956	4,874,390	22.19
1957	4,996,051	967,836	567,768	5,396,119	17.94
1958	4,905,786	927,442	99,783	5,733,445	16.18
1959	5,700,796	1,369,441	13,318	7,056,919	19.41
1960	5,348,435	1,453,692	16,350	6,785,777	21.42
1961	N.A.	1,793,266	123,911	-	-

* The Canadian shipments¹ figures may be incomplete inasmuch as they relate to Manufacturers of Pharmaceuticals and Medicines only, and do not include shipments which may have been made by establishments classified in other industries. Moreover, there is apparently some production by the medicinal and pharmaceutical preparations industry of penicillin and streptomycin not accounted for by these figures. See footnote 1, Table 3, p. 6 of Dominion Bureau of Statistics, The Medicinal and Pharmaceutical Preparations Industry, 1959.

Sources: Dominion Bureau of Statistics, Manufacturers of Pharmaceuticals and Medicines, 1960, Tables 3, 11 and 12, and corresponding tables from issues of previous years; Trade of Canada, Imports; Trade of Canada, Exports.

Table 4 shows that the domestic disappearance more than doubled from 1955 to 1960. This is interesting in view of the appearance of other antibiotics in this period. Imports, although they more than doubled from 1955 to 1961, were a lower percentage of domestic disappearance in 1960 than five years previously. Exports, which in 1955 accounted for 28.3 per cent of Canadian shipments had declined to an insignificant fraction of them by 1960. An increase in the dollar value of exports occurred in 1961.

It should be borne in mind that part of the imports are undoubtedly bulk drugs which are manufactured into dosage forms in Canada and that the percentages showing the relation of imports to domestic disappearance are not an indication of the competition of domestic and imported dosage forms at the retail level.

The figures in Table 5 show that the United States was the main source of Canada's imports of penicillin, although the American share of the total fell from 97.2 per cent in 1955 to 81.5 per cent in 1961. In 1955 and 1956 the United Kingdom was the second largest source of imports, but lost this position to Denmark in 1960 and 1961.

Similarly, United States was the chief source of imported streptomycin throughout the period 1955-61, although the American share of total imports fell from a maximum of 95.31 per cent in 1957 to 71.27 per cent in 1961. The other important sources were the United Kingdom and, in 1960 and 1961, Denmark.

Table 5

Sources of Imports of Penicillin and Streptomycin
and their Products, 1955-61

(\$)			
Year	Source	Penicillin	Streptomycin
1955	United Kingdom	19,426	50,120
	United States	675,661	143,563
	Total	695,087	193,683
1956	United Kingdom	30,620	18,336
	Austria	44,116	-
	Portugal	-	359
	United States	787,299	200,815
	Total	862,035	219,510
1957	United Kingdom	25,149	6,314
	Austria	60,672	-
	Denmark	15,531	-
	United States	731,864	128,306
	Total	833,216	134,620
1958	United Kingdom	61,636	34,584
	Austria	19,217	-
	Denmark	17,132	-
	Switzerland	9,385	-
	United States	646,517	138,971
	Total	753,887	173,555
1959	United Kingdom	87,456	34,588
	Austria	36,280	-
	Denmark	68,742	-
	France	3,715	-
	West Germany	-	312
	Netherlands	902	450
	Switzerland	-	3,535
	United States	873,034	260,427
	Total	1,070,129	299,312
1960	United Kingdom	59,403	47,958
	Austria	7,879	-
	Denmark	81,240	20,472
	Netherlands	6,099	864
	Switzerland	4,704	-
	United States	1,045,086	179,987
	Total	1,204,411	249,281
1961	United Kingdom	104,214	78,337
	Austria	405	-
	Denmark	153,866	32,494
	France	1,030	-
	Netherlands	-	373
	United States	1,146,685	275,862
	Total	1,406,200	387,066

Source: Dominion Bureau of Statistics, Trade of Canada, Imports, items 8083 and 8084.

Table 6

Canadian Domestic Disappearance
of Other Antibiotics, 1955-61

Year	Canadian ⁽¹⁾ (2) Shipments	Imports	Exports	Domestic Disappearance	Imports as per cent of Domestic Disappear- ance
	\$	\$	\$	\$	
1955	8,225,151	2,885,313	331,272	10,779,192	26.77
1956	8,593,450	2,880,637	307,822	11,166,265	25.80
1957	11,353,601	4,053,970	326,123	15,081,448	26.88
1958	13,023,490	4,431,941	195,365	17,260,066	25.68
1959	15,113,098	4,506,202	489,755	19,129,545	23.56
1960	15,725,029	3,378,639	1,140,028	17,963,640	18.81
1961	N.A.	5,983,028	984,462	-	-

(1) These figures refer to shipments by establishments classified as Manufacturers of Pharmaceuticals and Medicines by the Dominion Bureau of Statistics and do not therefore include shipments which may have been made by establishments otherwise classified.

(2) Apparently some penicillin and streptomycin are included. See footnote 1, Table 3, Manufacturers of Pharmaceuticals and Medicines, 1960, p. 7.

Sources: Dominion Bureau of Statistics: Manufacturers of Pharmaceuticals and Medicines, 1960, Tables 3, 11 and 12 and corresponding tables of earlier issues; Trade of Canada, Imports; Trade of Canada, Exports.

As shown in Table 6, domestic disappearance of other antibiotics rose by 66.65 per cent from 1955 to 1960. Although imports more than doubled in dollar value, they declined as a percentage of domestic disappearance. Exports have been of minor significance, their greatest importance having been in 1960 when they amounted to 7.25 per cent of Canadian shipments. Again, as in the case of the penicillins and streptomycins, the percentage relation between imports and domestic disappearance is not an indication of import competition in finished dosage forms.

Table 7

Sources of Imports of Other Antibiotics,
1955-61

(\$)		
1955	United Kingdom	218,767
	France	8,082
	United States	<u>2,658,464</u>
	Total	<u>2,885,313</u>
1956	United Kingdom	128,164
	Denmark	270
	France	33,738
	United States	<u>2,718,465</u>
	Total	<u>2,880,637</u>
1957	United Kingdom	94,552
	Denmark	3,715
	France	8,711
	Switzerland	3,105
	United States	<u>3,943,887</u>
	Total	<u>4,053,970</u>
1958	United Kingdom	124,791
	Denmark	7,364
	France	57,915
	Switzerland	9,095
	United States	<u>4,232,776</u>
	Total	<u>4,431,941</u>
1959	United Kingdom	269,368
	Denmark	37,044
	France	40,987
	West Germany	23,207
	Switzerland	2,050
	United States	<u>4,133,546</u>
	Total	<u>4,506,202</u>

Table 7 (cont'd)

1960	United Kingdom	218,486
	Czechoslovakia	6,938
	Denmark	47,243
	France	17,638
	West Germany	77,136
	Italy	78,998
	Netherlands	1,066
	Switzerland	833
	United States	<u>2,930,301</u>
	Total	<u>3,378,639</u>
<hr/>		
1961	United Kingdom	269,903
	Belgium and	
	Luxembourg	13,224
	Czechoslovakia	129,858
	Denmark	46,723
	France	20,754
	West Germany	97,357
	Italy	151,096
	Netherlands	1,264
	Switzerland	21,933
	United States	<u>5,230,916</u>
	Total	<u>5,983,028</u>

Source: Dominion Bureau of Statistics, Trade of Canada, Imports, item 8086.

From Table 7 it is clear that the United States is the main source of imports of other antibiotics. The United States accounted for 92.14 per cent of total imports in 1955, and 97.28 per cent in 1957, but since then its share of the total has fallen, reaching 87.43 per cent in 1961. The United Kingdom was the second most important source of imports throughout the period while in 1960 and 1961 Italy, Czechoslovakia, and West Germany increased in importance in this respect.

5. Classification of Pharmaceutical Establishments by Volume of Production

Classification of pharmaceutical manufacturing establishments according to the value of factory shipments in 1953 and 1960 is shown in Table 8. It will be seen from this table that in 1953 the 4 largest establishments accounted for 26.09 per cent of the total value of factory shipments and the 22 largest for 62.66 per cent. Similarly, in 1960, the 9 largest establishments had 40.77 per cent and the 40 largest 83.55 per cent of the total. The deduction might be made that these statistics show that there is not a high degree of concentration in the industry. This deduction would be subject to the reservation that establishment and firm are not synonymous, that one firm may own more than one establishment and that, therefore, the degree of concentration may be higher than is shown by the statistics and the percentages derived from them. It would also be necessary to take into consideration the point which is discussed below, viz., the extent to which the products of different plants are competitive.

Table 8

Medicinal and Pharmaceutical Preparations Industry
Establishments Grouped According to Size
1953 and 1960

Establishments Reporting a Value of Factory Shipments	1953			1960		
	Number of Establish- ments	Selling Value of Factory Shipments	Per cent of Total Shipments	Number of Establish- ments	Selling Value of Factory Shipments	Per cent of Total Shipments
		\$			\$	
Under \$10,000	38	187,944	0.20	29	140,562	0.09
\$10,000 to	28	464,211	0.50	22	370,728	0.22
\$25,000 to	21	729,114	0.78	21	716,685	0.43
\$50,000 to	28	2,031,556	2.17	15	1,080,500	0.66
\$100,000 to	28	3,967,823	4.24	23	3,374,140	2.05
\$200,000 to	25	7,940,469	8.49	32	10,565,422	6.40
\$500,000 to	27	19,613,480	20.96	16	10,878,510	6.60
\$1,000,000 to	18	34,210,152	36.57	31	70,546,467	42.78
\$5,000,000 and over	4	24,412,419	26.09	9	67,223,752	40.77
Total	217	93,557,168	100.0	198	164,896,766	100.0

Sources: Dominion Bureau of Statistics, The Medicinal and Pharmaceutical Preparations Industry, 1954, Table 7, p. E-7, and
Dominion Bureau of Statistics, Manufacturers of Pharmaceuticals and Medicines, 1960, Table 7, p. 10.

Dr. Brian Dixon, Assistant Professor, Commerce and Business Administration, Queen's University, and Consulting Economist, Kingston, Ontario, draws certain conclusions regarding the degree of competition in the pharmaceutical manufacturing industry:

" . . . However, a reasonably good measure of concentration can be obtained from a classification of establishments by sales volume found in the Pharmaceutical Industry Annual [Dominion Bureau of Statistics, Manufacturers of Pharmaceuticals and Medicines, or the title used in previous years, The Medicinal and Pharmaceutical Preparations Industry] .

In 1958, eight establishments shared 41% of factory sales volume, and an additional 29 shared 43% of the factory sales. Thus 37 establishments shared 84% of the factory sales, with an additional 16 firms, combining to share 90% of the business, the remaining 10% being shared by the other 143 firms. Thus the total of firms in the industry as a raw statistic must be modified by the fact that many of these establishments are obviously very small . . . However, the number of establishments of significant sales volume, as indicated in the Annual, does not indicate a particularly high degree of concentration. It allows for several dozen establishments with sales volumes and shares of the market adequate to provide a vigorous stand in the market.

. . .

Comparing the figures for 1958 with the previous years back to 1953 (when this information first began to be published), it would not appear that there has been any significant change in the concentration. In 1955, 24% of the establishments shared 85% of the business, while in 1958 27% shared 90% of the business. When it is considered that some of the smaller firms are regional rather than national in market coverage, this tends to increase the number of firms effectively competing for market share in any given market. Although the regional firms will be small in relation to the large national firms, their sales volume in their own area can give them a better relative position in that particular. In addition, with only regional distribution and promotion with which to contend, instead of the relatively high costs of both intensive and extensive distribution over the limited Canadian market, the relative competitive strength of some of these smaller firms is further improved.

It would appear then, that the degree of concentration in the industry is not of an order to prevent effectively competitive conditions from prevailing in the market, . . ."(1)

Dr. Dixon was asked by counsel for the Director whether his conclusions would not be dependent upon the degree of homogeneity which existed among the products of the various pharmaceutical manufacturers. Dr. Dixon referred to the fact that in some lines, such as tranquillizers, a number of firms offer products and he considered that there is also a considerable area in which cross-substitution could occur, such as between barbiturates and tranquillizers. He did not consider, therefore, homogeneity would be the determining factor in his conclusions (Hearing, pp. 3022-23).

In view of the evidence heard by the Commission as to specialized use of drugs and as to the degree of loyalty which doctors exhibit in their prescribing of drugs (see section 6 of Chapter V and section 8 of Chapter VI) the Commission cannot agree with the opinion expressed by Dr. Dixon that the statistics classifying establishments according to volume of production provide a really dependable measure of the degree of competition which exists in the pharmaceutical manufacturing industry. It appears to the Commission that a much more detailed analysis would have to be made of the positions occupied by individual companies with respect to particular classes of drugs and the extent to which medical doctors regard drugs as substitutable before any definite conclusions could be reached.

While the following portion of the brief of the Canadian Pharmaceutical Manufacturers Association suggests a degree of potential competition in the efforts of individual manufacturers to broaden their product lines it also indicates, to some extent, the amount of specialization which exists in the industry:

"To retain its position in the Canadian market, a company must spread its cost over many products. It could not take the chance of limiting itself to one major field such as ataractics or antibiotics.

(1) Dr. Brian Dixon, An Economic Analysis of the Pharmaceutical Manufacturing Industry, September 15, 1960, pp. 6-8.

As is noticeable from the overall decline in antibiotics and ataractics this year, companies are constantly faced with a fluctuating rise and decline in sales from product to product. A company may conceivably find itself in first or second place on antibiotic sales this year. Next year, it might be in fifth or sixth place. If a competitor brings out an improved product in the same therapeutic class, its sales are bound to affect those of the first company. Accordingly, the first company must have some other major products to help carry the loss to its antibiotic sales. Plummeting sales of a large-volume product can materially change a company's entire financial picture.

For this very reason, it is not practical to base a company's entire operations on one or two products, such as antibiotics or ataractics. We must base our findings on the company's overall operations, and this is equally true at the industry level. This was borne out in the recent survey referred to earlier. Thirty-five companies indicated the following:

- 10 make both antibiotics and ataractics;
- 12 make antibiotics but no ataractics;
- 5 make ataractics but no antibiotics;
- 8 make neither antibiotics nor ataractics.

Thus, 20 of these 35 firms make no ataractics, while 13 make no antibiotics, and these are all major companies in the industry."

(Association brief, pp. 11-12; Hearing, pp. 1822-23)

The opinion expressed in the foregoing extract is that a manufacturer may find his sales affected if a competitor brings out an improved product in the same therapeutic class. This, of course, may be a different drug from that which previously had been chiefly relied on by the medical profession. Developments of this kind have significant competitive effect but this competition takes place within therapeutic classes. It may be noted from the tabulation given in the quotation above that in the group of 35 firms⁽¹⁾, 22 manufacture one group of products of the same therapeutic class (antibiotics), 15 make products of another class (ataractics) while 8 firms make neither class of drug.

(1) These 35 firms are identified in Exhibit T-6, Survey No. 5.

6. Manufacturing Activities of Ethical Drug
Firms

As indicated in an excerpt from the brief of the Canadian Pharmaceutical Manufacturers Association, it is estimated that of the 188 establishments reporting to the Dominion Bureau of Statistics about 70 are multi-line ethical pharmaceutical manufacturers and about 75 are multi-line proprietary manufacturers. The Canadian Pharmaceutical Manufacturers Association represents 56 companies engaged in manufacturing and distributing ethical pharmaceutical preparations, including some non-manufacturing subsidiaries of foreign manufacturers as associate members.

The survey of the operations of pharmaceutical manufacturers in 1960 made on behalf of the Association, to which reference has already been made, showed that about 84 per cent of the sales of the 40 firms reporting consisted of human pharmaceuticals.

The following comments on the significance of imports of drugs in relation to manufacturing in Canada are made in the brief presented by the Canadian Pharmaceutical Manufacturers Association:

"Based on the shipment figure of \$186,762,000, imports were about 17 per cent of the total for the year. This is significant in light of the various statements in the green book which have created, and we believe unintentionally, the misconception that the large percentage of ethical pharmaceuticals are imported.

If we discount the importers, and there are a large number of these in Canada, the percentage of imports by ethical manufacturers are extremely low in relation to Canadian production. This is further borne out by a survey of 28 companies which we undertook in 1960, indicating clearly that these firms manufacture in Canada 94 per cent of their products, and import only six per cent.

Nor was there any significant difference according to financial control. The wholly-owned Canadian firms manufacture 98 per cent of their products in Canada; the U.S. subsidiaries, 92 per cent; and the European subsidiaries, 94 per cent.

The firms covered in this survey were manufacturers and not merely distributing companies. In another survey of 40 firms, which included non-manufacturing members, we found that 81.5 per cent of the total sales volume was manufactured and packaged in Canada, 11.8 per cent was made outside Canada but packaged here, while 6.7 per cent was manufactured and packaged in other countries."

(Association brief, p. 8; Hearing, pp. 1812-17)

The testimony of Mr. S.N. Conder, General Manager of the Association, makes clear that the percentage figures of imports in relation to total sales have reference to the value of the finished product in dosage form. In view of the information given in the Green Book as to the cost of bulk chemicals or drugs in relation to manufacturers' selling prices of drugs in dosage forms, such percentages give little indication of the extent to which basic drugs are manufactured in Canada.

The Green Book (pp. 63-64) lists the names of the 27 firms in Canada which reported the largest sales of ethical drugs and also the names of the foreign parent or controlling company in the case of those Canadian companies which are subsidiaries. Of the companies listed, only two, Charles E. Frosst & Co. and Frank W. Horner Limited⁽¹⁾ are shown as not being affiliated with a foreign company.

The relationship existing between the subsidiary companies in Canada and the parent organizations in the United States was viewed by the Director as leading to the following situation:

"... The great majority of large ethical drug firms operating in Canada are branches or subsidiaries of United States firms and import not only basic drugs from the U.S. but, in many instances, prepared dosage forms and simply package them in Canada. It is quite clear, therefore, that when 'foreign' produced drugs are criticized, it is European drugs which are referred to.

(1) Early in 1962 it was indicated in trade reports that Carter Products Inc. of the United States had acquired a controlling interest in Frank W. Horner Limited (The Conference Board Business Record, April, 1962, p. 42)

Of course, on economic grounds, it makes little difference from which country drugs are imported. Importations from the United States do not assist in developing Canadian production facilities any more than do importations from other countries. There may be other reasons why drugs manufactured in the United States should be purchased in preference to those manufactured in Europe, but if such reasons exist, they do not appear to be economic."

(Green Book, pp. 14-15)

While agreeing with the Director on the position occupied by subsidiaries of American companies in the ethical pharmaceutical industry in Canada, the Canadian Pharmaceutical Manufacturers Association took issue with the Director's view that there is little difference from what country importations of drugs are made. The position of the Association is set out in the following portion of its brief:

"As we mentioned earlier, our Association primarily represents companies which manufacture under their own names in this country, but we also include in our membership as Associate Members, non-manufacturing subsidiaries of foreign manufacturers which maintain adequate quality control facilities.

Most of our present Full Members which are subsidiaries of foreign corporations, originally started out on a small basis without Canadian production facilities. In time, their volumes eventually reached the point where it was economical to set up plants in this country.

Based on our experience in this area, we take issue with the statement on page 15 of the green book which opines that 'importations from the U.S. do not assist in developing Canadian production facilities any more than do importations from other countries'. As a flat statement, without qualification, this is incorrect.

It is an historical fact that U.S. importing subsidiaries have eventually established more manufacturing plants here than all other countries combined. In these cases, importations from the U.S. have resulted in developing Canadian production facilities to a greater extent than any other single source. Furthermore, the great majority of these subsidiaries are headed up by Canadian-born management who consider their operations wholly Canadian. This is offered merely as a matter of fact, for

we hold no particular brief for U.S. subsidiaries over those of other countries in our Association's day-to-day operations."

(Association brief, p. 20; Hearing, pp. 1848-49)

As in other fields of manufacturing the close proximity of the United States and Canada has undoubtedly made it easier for American drug companies to establish subsidiaries in Canada than would be the case for manufacturing companies overseas although there are some notable instances in Canada of undertakings of the latter kind. Another influence of considerable importance has been the relationship between the medical professions in Canada and the United States, which means that promotional programmes by drug manufacturers in the United States are likely to assist in the promotion of the products in Canada.

CHAPTER V

MEDICAL RESEARCH IN CANADA

1. Kinds of Research

A distinction is sometimes made between pure research and other types of research, and this distinction was referred to by more than one witness in the present inquiry. Although none of the witnesses specifically used the term "industrial research" it seems desirable to have some name to indicate that type of research which is not thought of as being pure research. The term "industrial research" is explained in the following quotation:

"Industrial research does not necessarily differ from so-called pure research in its methods; it is the object with which the investigation is made that constitutes the difference; and of course much work is necessary before the laboratory discovery, or the brilliant intuition of the inventor, verified by striking experiments, can be translated into the practice."⁽¹⁾

A distinction between research and development was made by Dr. L. B. Pett, Principal Medical Officer for Research Development, Department of National Health and Welfare, in the following excerpt from his testimony:

"MR. MACLEOD: Well, in your opinion, as a man with some knowledge of the field, is there a difference between the type of research carried out by commercial drug firms on the one hand and by teaching hospitals and such institutions on the other? Is one more basic than the other? Is one more directed towards immediate results or anything like that?

DR. PETT: I think it might be answered, Mr. Chairman, by me defining 'research' before I answered. Better men than I have stumbled on trying to define research. I prefer a very simple definition personally and one that I have defended before the Royal Society and other scientific bodies: namely that 'research is the systematic attempt to add to

(1)

The Encyclopedia Britannica, Fourteenth Edition, Vol.19, p.204.

knowledge'. It has to be systematic to be scientific and you have to have a plan and method, you see. Its objective is to add to knowledge. You can get much more elaborate definitions but I like this one personally.

THE CHAIRMAN: It probably covers the field.

DR. PETT: It is rather broad.

It does, however - and this is in answer to your question, sir, tend to eliminate a number of things that are often called research. If you merely make a new chemical, have you in fact added to knowledge?

Now, I would be inclined to say 'no'. If you studied what that chemical does systematically to humans, what its effect on diseases might be and that sort of thing, this becomes research. You see you can add to knowledge that was not previously known.

But I think that this other aspect, which is quite commonly called in industry with which I am familiar, not only primarily the chemical industry, is called development or sometimes developmental research; really has to be separated off from true research because developmental work does not really add to knowledge. It adds maybe more names and compounds but it doesn't really add to knowledge.

THE CHAIRMAN: It might add to the uses for the material.

DR. PETT: It might ultimately, yes sir.

. . .

MR. MACLEOD: Yes. Now, having defined research, would you care to express an opinion on the question I originally asked you about whether there was a difference in the type of research carried on in teaching hospitals and such places as compared with drug firms.

DR. PETT: Yes, I think there is a very great difference. All the research I know of in drug firms is concerned primarily with the production of some new or different product which may or may not at that stage be needed for the treatment of any particular health problem at the time; whereas in universities and teaching hospitals they are concerned with a problem.

They have patients that have to be treated and they want to understand as fully as possible the best way of treating them, whether it is with an old familiar drug or a new one so they are concerned with quite a different aspect of the subject."

(Hearing, pp.233-36)

The distinction between basic research and practical research is considered by Dr. Roger Larose, Dean of the Faculty of Pharmacy at the University of Montreal, in the following quotation:

"The question is often asked 'Where does basic research end and where does practical research start?' Some consider basic research as the idle pastime of impractical dreamers; some hold basic research in an almost religious awe. At the opposite, you will find those who disregard research that does not yield obvious benefits and those who turn their noses down at what they term practical research because its yield is marketable.

The truth is that these two forms of research are two aspects of the same human endeavour. Both are essential to human progress.

When Pasteur conducted his famous experiment of keeping a piece of meat in vacuum to show that the corruption of meat exposed to air pollution was caused by living micro-organisms and not by spontaneous growth of corrupting factors, he was doing basic research. When the same Pasteur produced his first serum that cured a dying child, he was doing practical research.

When Lyster applied Pasteur's theories to aseptic surgery and Semmelweis applied them to antisepsis in obstetrics, both were doing practical research. Enders by his basic research on cells and cultures made it possible for Salk to do his practical research; both gave the world the polyomyelitis vaccine.

. . .

. . . Development is an important function in the coming to life of a medicament. It is a function which is frequently shared by the pharmaceutical industry, although not always, with universities, research institutes, and hospitals. Development consists in taking over a substance produced by research, qualifying it by pharmacology and toxicology, properly identifying

it by analysis and bringing it over to the consumer in its pharmaceutical form.

It involves galenical or pharmacy research, that is, the actual development of the pharmaceutical form, the procurement and processing of raw material, the pilot plant operation, the designing of equipment and plants, and countless assays and tests. To quote only a very few examples: Penicillin, cortisone and the Salk vaccine were brought to the market by the pharmaceutical industry in collaboration with hospitals, universities and research institutes. While it was said recently that penicillin was entirely developed through government financing, which is far from the truth, cortisone was almost entirely developed by one pharmaceutical firm out of its own financial resources. But it could not have done it without the collaboration of the other groups.

To underline the importance and the cost of development, let me point again to penicillin. Its action was first observed by Fleming in 1928. The Oxford team of Florey and Chain made it into a purified crystalline substance between 1936 and 1939. Florey, Chain and Heatley tried it on small animals and verified its antibiotic action and its absence of toxicity in 1940. The same year Heatley tackled the problem of larger production while Chain and Abraham purified the quantities produced by Heatley.

It was first tried on a human being in 1941; the Northern Regional Research Laboratory in the United States, at the urging of Florey, worked out a larger scale fermentation process. Finally in 1943, 15 years after Fleming's original observation, the British and American Pharmaceutical Industry joined their efforts into producing penicillin commercially. This is a classical case.

The spark flashed in a hospital laboratory; the original development work was done at Oxford with the assistance eventually of a research institute in the United States. Because of the war emergency, the British Government was invited in to co-ordinate and speed the effort; mass production was achieved by the pharmaceutical industry."⁽¹⁾

(1)

Dr. Roger Larose, "Research, Development and Production", Canadian Pharmaceutical Journal, September 1960, Vol. 93, No. 9, pp. 61-62.

A description of the interrelationship between research done in the university, the drug company's laboratory and hospitals, and a chronology of the steps in the discovery, development, and testing of a new drug are contained in the following excerpt from the brief of Dr. M. Darrach, Professor and Head of the Department of Biochemistry, Faculty of Medicine, University of British Columbia: (1)

"B. Discovery and Development of Drugs

Historically, research related to the development of new therapeutic agents has almost always involved a cooperative effort between the research personnel of the University and industrial drug laboratory in the early stages and between University hospital clinics and the drug industry's medical departments in the latter stages.

Chronologically the steps usually associated with the development of new drugs are as follows.

The Original Idea

The original concept for a new and useful substance may arise from one or more of a number of sources. 1) It may be a new application of a known substance (e.g. sulfanilamide¹ first made in 1908 but not used for treating infections until 1935, or potassium iodide² known and available in the 19th century but not in general use for the prevention of goiter through iodized salt until 1921). 2) The original idea may emerge from a University research laboratory as an incidental development of some broad basic research problem (e.g. Fleming's discovery of penicillin³). 3) It may be conceived in a University laboratory working in collaboration with scientists in a drug company (e.g. Waksman's discovery of streptomycin). 4) The original idea may emerge from a drug manufacturing laboratory which is normally motivated towards the deliberate creation of new and better drugs (e.g. the isolation of vitamin B₁₂ by the Merck laboratories)⁴. Thus the original idea may stem from a scientist or group of scientists working in laboratories anywhere in the world.

The Preparation of Pure Material in Small Amounts for Laboratory Testing

This phase in the development of new drugs usually presents a frustrating bottleneck requiring a very large research effort.

(1)

Marvin Darrach, Ph.D. "Importance of Medical Research", August, 1961, pp.2-6.

The substance, although showing some promise, is generally of undetermined value and there is always the question of whether the research effort would be worthwhile in time and money. The problem, for example, may involve an extraction from large amounts of material (e.g. R.R. Williams' isolation⁵ of vitamin B₁ from tons of rice bran polishings). Usually the University laboratory is not able to cope with such problems and collaboration with a drug manufacturer who has the appropriate equipment is common practice among scientists.

The new drug, on the other hand, may involve a difficult synthesis which normally is not appropriate for a University medical research laboratory. Here again the drug manufacturing laboratory with its highly skilled organic synthesis group is often called upon for assistance.

The purification of extracts or fermentation beers (e.g. insulin, penicillin⁶, streptomycin) so important for this early research phase and for the elimination of toxic extraneous matter has traditionally been a major contribution of the drug industry's laboratories.

At the early stage in the progress of drug development, the drug manufacturing laboratories render a vital, indispensable, but usually unrewarding service as their part in the collaborative effort.

Laboratory Tests for Biological and Chemical Properties

Once a small amount of a pure substance of theoretical interest has been prepared, the study of its properties begins. If possible it is characterized chemically and its detailed structure elucidated. Its biological properties are investigated in detail, e.g. its effect on experimental animals, on the growth of bacteria, viruses or cancer cells. The toxicity of the substance must be established in several species and any possible side effects predicted. Its effect on the biochemistry of the body is determined as well as the manner in which the substance is stored, metabolized and excreted. If the substance shows activity of interest, the effect of various routes of administration such as oral, intravenous and intramuscular, must be determined. Research in these fields is often a co-operative effort between the University, private or drug industrial laboratories. Usually the strongest motivation for such investigation is with the Drug Industry in its search for new products and thus the burden of most of this work is normally carried by their laboratories.

Initial Clinical Trials

Once the reasonable safety of a substance has been established as well as its biological properties, the material may be ready for testing in humans. In this area of research the medical division of the drug company and the clinical research staff of a hospital or medical school assume primary responsibility. Good clinical judgment based on experience is of most importance during these early assessments of a drug's potential value. The patients must be selected with great care and studied in detail by all appropriate scientific methods. The attending physicians must be alert to side effects and must judge the new treatment against other available methods. Adequate controls are essential to assess the true value of the drug's activities. Such studies are often time consuming and the desired data may not be available for months or even years. Obviously such undertakings are expensive and require the most able clinicians available. The driving force behind such investigations in the research for new drugs are the medical scientists of the drug companies in collaboration with their medical colleagues in the research clinics.

Pharmaceutical Forms

During the clinical trials of new substances, the drug companies must take full responsibility for supplying the material in the best pharmaceutical form. This requires research for every new product. Sometimes the problem is relatively simple, at other times exceedingly complex. Such factors as potency, stability, purity, release, compatability, allergic properties, flavour, etc. must be considered. They constitute a major research effort conducted entirely in most instances by the drug manufacturer.

Broader Clinical Testing

If the small scale clinical trials prove successful and adequate dosage forms have been established as well as a clear understanding of the potential hazards involved, the new substance may be released for clinical trials on a larger scale. At this time certain specialists in general practice may become involved and numerous research and treatment clinics throughout the world will study the new drug and sit in judgment of its potential value. Here is the crucial test. To be acceptable to the medical profession, the new therapy must show more advantages and less disadvantages than established forms of treatment.

Production Problems

Based on the evidence from clinical trials a decision is made by the drug manufacturer as to whether he should or should not proceed with large scale production of the new drug. In preparation for this he will normally have conducted extensive research into various production methods for the purpose of reducing costs, improving quality and yields, on a scale adequate to meet the expected market needs. Production research is of great importance and is usually carried on from the time the drug is first produced in the laboratory, through pilot plant operations and into manufacturing. Of greatest concern to the ethical drug manufacturer is the matter of quality control; throughout the processing, potential sources of contamination from raw materials and side reactions must be known for the establishment of adequate safety controls.

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2. Non-Profit Institutions Carrying on or Supporting Research

The Green Book (pp.120-27) contains detailed information with respect to non-profit institutions carrying on medical research in Canada. It gives a list of institutions supporting such research and an account of the Canadian Government's contribution from 1946-47 to 1959-60. Total funds available from all sources are indicated for the years 1949-50, 1952-53 and 1955-56. There is nothing to be gained by repeating this material in the present report. The following extracts from the evidence given to the Commission are designed to clarify the nature of the research done by the institutions named in the Green Book.

Dr. L. B. Pett, Principal Medical Officer for Research Development, Department of National Health and Welfare, testified as follows about the responsibilities of the Research Development Section of the Department of National Health and Welfare:

"The Research Development Section is assigned the following responsibilities:

- (a) Scientific appraisal, in consultation with medical research experts, of research projects under the National Health Grants Program whereby grants-in-aid of medical research are made through provincial departments of health for research carried out in universities, hospitals, and other places.
- (b) Advising the department on research policies.
- (c) Maintenance of liaison with other agencies making medical research grants or conducting research, e.g. the Medical Research Council of Canada, Defence Research Board, Department of Veterans' Affairs; Voluntary Agencies such as the National Cancer Institute, National Heart Foundation, Canadian Arthritis and Rheumatism Society, and research institutes such as the Connaught Medical Research Laboratories, they are in Toronto, the Institute of Microbiology and Hygiene, which is in Montreal, and some other institutes.

Diseases and disabilities of special interest in the National Health Grants Medical Research Program are categorized here under four headings:

- (a) Infectious diseases, including all those commonly encountered in Canada, e.g. tuberculosis, poliomyelitis, measles, etc., and unusual infections, e.g. Asian influenza.

(b) Chronic diseases, or those requiring prolonged treatment, mainly cardiovascular, cancer, mental disorders, and rheumatic diseases.

(c) Disease and disability arising from environmental conditions, including air and water pollution, ionizing radiation and accidents.

(d) Other disease problems involving genetics, maternal and paediatric conditions, occupational hazards, etc.

The research projects which are assisted by the National Health Grants range widely over many aspects of medicine, but with special emphasis on the areas just mentioned.

During the current fiscal year [1961], out of 323 research projects assisted by the Department of National Health and Welfare only 18 are in the field of pharmacology and therapeutics, and none of these 18 is concerned with the preparation of new drugs. Funds for these research projects amount to about \$195,000 this current fiscal year, or approximately 6 per cent of the total for research under the National Health Grants Program.

THE CHAIRMAN: That \$195,000 does that refer to the 18 projects?

DR. PETT: Yes, sir. I thought these facts would be of interest to you. It is not really a submission, but facts from our program.

None of these moneys is directed to the drug industry nor is there otherwise any formal contact with drug manufacturers under the Research Grants Program.

I want to make clear that the Section is not concerned in any direct way with the drug industry.

Within the Department, research related to drugs, is almost entirely carried out in the Food and Drugs Directorate."

(Hearing, pp.218-20)

Dr. Pett also testified as follows:

MR. MACLEOD: And before approving research for a certain purpose, would you check to see if there was research

in that field being carried on by the commercial drug companies, or would you have sufficient general knowledge of the field to know that?

DR.PETT: No, well, yes we would check to find out if there was research in that field, or whether it was an important subject for research, whether it was a developmental program. We would not have, and when I started with a no, I was referring to the latter part of your question, we would not have all the knowledge necessary to cover all the fields of medicine or pharmacology. [It is] for this reason, that we carry on consultations with experts in the fields. We might and do consult appropriate people, even employed by industry or in universities, or anywhere else, as to the advisability of supporting a given research program.

MR. MACLEOD: What I was getting at was this, whether the fact that you provide the expenditure of money for research in a certain field or certain area, means that nobody else in Canada is carrying on that research, and you feel it is necessary and desirable that it should be done?

DR.PETT: No sir, it does not mean that. It is quite possible that research on the same subject, or closely allied aspects of the same subject, might be carried on several places in Canada at once."

(Hearing, pp.221-22)

During his appearance Dr. Pett was asked if he could make a comparison of the amount of research which was government-supported and that conducted by commercial drug firms. Dr. Pett pointed out that research projects sponsored by the government are concerned not so much with new products as with the use of products that are available. He said that he did not know of an agency which keeps a record of all medical research which is conducted in Canada but from those surveys of which he had knowledge he had gained the impression that research carried on by commercial drug firms would form a minor part of total medical research in Canada. However, Dr. Pett added that he would become aware of the research work of drug firms primarily through the publication of reports in professional journals which would usually appear at a late stage of the work (Hearing, pp.223-227).

Dr. Pett testified as follows on the location of the chief centres of medical research in Canada:

"MR. MACLEOD: Are the chief centres of research in the medical field the teaching hospitals and such places as

Connaught Laboratories and the Institute of Microbiology in Montreal?

DR. PETT: Well, the universities themselves - the university departments themselves do a great deal of medical research and they may or may not be working in and with the teaching hospitals. Those can be quite separate from that. I would say first of all for medical research, all of the medical faculties, and there are 12 in Canada right across the country, are at least potential sources of medical research and I think everyone of them has medical research going on.

Then affiliated with them, certain departments in hospitals. Then you also have quite independent research in hospitals where you get an investigator who wants to carry it out and then you have these separate institutions which you have mentioned.

MR. MACLEOD: Are the two I have mentioned the most important in Canada of that type?

DR. PETT: Yes, I think so.

Perhaps I am neglecting to mention here there is the Banting and the Best Medical Research Institute and also the Charles H. Best Institute in Toronto but these are so closely affiliated with the university that I think I am perhaps neglecting them just a trifle. They do outstanding work."

(Hearing, pp.238-39)

3. Expenditures of Canadian Pharmaceutical Manufacturing Companies upon Research

Table XXIV of the Green Book (pp.108-10) shows the percentage relationship of expenditures on research to net sales for 27 selected firms for the calendar year 1959 or the company's financial year most closely approximating the calendar year. The proportion of net sales expended upon research or in the form of grants to hospitals, universities, etc., varied from zero to a maximum of 8 per cent.

Tables 9 and 10 show the total expenditures upon research and development by 22 Canadian pharmaceutical manufacturing companies in 1958 and 1959, and by 35 such companies in 1960. The material condensed in these tables was supplied to the Commission by the Canadian Pharmaceutical Manufacturers Association. Its source was described as follows:

"The following page contains the results of two surveys of the research and development expenditures of our member companies: One covers 22 companies for the years 1958 and 1959 undertaken by C.P.M.A.; the other covers 35 companies for the year 1960, undertaken by Clarkson Gordon & Company of Toronto. For this survey, we asked the companies to break down their research and development expenditures incurred in Canada. In addition, we asked for the share of research and development costs charged to subsidiaries by parent corporations for research undertaken in other countries, on the grounds that this amount of money must be reflected in Canadian prices."

(Association brief, p.36; Hearing, pp.1889-90)

Table 9

Research and Development Expenditures by 22 Companies
in 1958 and 1959

	<u>1958</u>	<u>1959</u>
Spent abroad by foreign parent companies on behalf of Canadian subsidiaries	\$2, 288, 757	\$2, 614, 900
Actually spent in Canada	2, 238, 185	2, 500, 165
Research Projects underwritten abroad by Canadian firms	<u>191, 828</u>	<u>209, 548</u>
Total cost applicable to firms operating in Canada	\$4, 718, 770	\$5, 324, 613
Total cost as percentage of net sales	6.3 per cent ⁽¹⁾	
Selected Items Included in total cost:		
Clinical Investigation	\$ 302, 288	\$ 362, 889
Research gifts and grants	298, 358	327, 784
Capital expenditures on research and development laboratories and equipment in Canadian plants	1, 266, 582	2, 456, 322

(1) It was indicated in the evidence (Hearing, p.1891) that this percentage represented the proportion for the two years.

Table 10

Research and Development Expenditures by 35 Companies in 1960

Spent abroad by foreign parent companies on behalf of Canadian subsidiaries	\$6,202,000
Actually spent in Canada	<u>3,349,000</u>
Total cost applicable to firms operating in Canada	\$9,551,000
Total cost as percentage of net sales	8.3 per cent
Selected Items Included in total cost:	
Clinical Investigation	\$1,022,000
Research gifts and grants	414,000
Capital expenditures on research and development laboratories and equipment in Canadian plants	2,968,000

Source: Brief of the Canadian Pharmaceutical Manufacturers Association, p.37.

Mr. Conder, General Manager of the Association, explained that the percentage relationship of expenditures on all research and development to sales shown as 6.3% and 8.3% was larger than the percentage derived from the Director's figures, because the Director's data were for expenditures on research actually done in Canada by the companies involved, whereas the Association brief takes into consideration the amount of research charged against the operations of Canadian subsidiaries by foreign parent companies which engage in research abroad (Hearing, p.1891).

With regard to the item "Research Projects Underwritten Abroad by Canadian Firms", Mr. Conder testified that such expenditures would be made primarily by wholly-owned Canadian companies which underwrite a specific research project in a foreign research establishment which might be following a certain line of inquiry or which might have facilities not available in Canada for this work (Hearing, p.1892).

As to the relative size of the expenditures, the Association brief stated:

"Referring to the survey covering 22 firms for the years 1958 and 1959, it is interesting to note that these companies spent more on pharmaceutical research in Canada in 1958-59 than that expended by either the National Research Council or the Department of National Health and Welfare for extramural medical research, as reported in the green book. And the term medical research in respect to these two government agencies is not limited to pharmaceutical research. Furthermore, the voluntary health agencies interested in specific diseases such as arthritis, cancer and muscular dystrophy, cannot be considered an effective alternative to general pharmaceutical research. A large portion of their funds must necessarily be spent on education, and the expenditures on research by these agencies go towards medical research in its broad application.

It is for these reasons that we question the comment in the green book that 'research in Canada appears to be regarded more and more as a responsibility of government and of those private organizations interested in particular diseases'. In the field of drug research Canada's pharmaceutical manufacturing industry is presently doing its share of investigation."

(Association brief, p.38; Hearing, pp.1896-97)

The Green Book (para. 211,p.130) states that the total sales of the 22 firms listed in Table XXVII of the Green Book were \$94.6 million and that the average expenditure on research by those firms was 2.12 per cent of sales. As explained in para.210 of the Green Book, these figures are for the year 1959 or the last financial year if the respondent company's financial year did not coincide with the calendar year. With respect to these figures, the brief of the Canadian Pharmaceutical Manufacturers Association stated:

"However, there is one rather notable discrepancy. The 22 firms mentioned in the green book are reported to account for total sales of \$94, 600, 000 whereas our own annual statistical

figure for the same period shows 43 firms with a total sales of human pharmaceuticals of \$96, 516, 511. Even though some of the firms mentioned in the green book were not covered in our survey, it is doubtful that 22 companies would account for only about \$2, 000, 000 sales.

As the author of the green book will no doubt agree, statistical percentages can be confusing unless the same terms of reference are used in comparisons. For this reason, we venture that this \$94, 600, 000 figure shown in the green book undoubtedly represents total sales of all products manufactured by most of the companies in question and not merely that of human pharmaceuticals. For instance, our survey produced a total sales for 43 firms of \$130, 755, 546, whereas only \$96, 576, 511 of that was in human pharmaceuticals. The balance, \$34, 239, 035, comprised chemicals, proprietary medicines and other products. If this is the case, then the percentage of research expenditures to sales mentioned in the green book is lower than it should be, on the premise that the ratio on research for ethical pharmaceuticals should be limited to sales of ethical pharmaceuticals.

Carrying this approach to its conclusion, we suggest that the green book's percentage of research should be closer to 3.1 per cent of sales rather than 2.1 per cent. This reasoning is based on the fact that our own survey for the same year showed a percentage to sales of 6.3 per cent, and this included research assessments against Canadian subsidiaries by foreign parent companies. As this assessment dollar-wise represented about half the total research figures of 6.3 per cent, the balance would work out to about 3.1 per cent for actual expenditures in Canada. Again these figures are close enough to warrant accounting comparison."

(Association brief, pp.39-40; Hearing, pp.1898-99)

A publication of the Dominion Bureau of Statistics entitled Industrial Research-Development Expenditures in Canada, 1959 ⁽¹⁾ shows the percentage relationship of direct research-development expenditures to sales for 15 major industries in Canada. For chemical

(1)

Dominion Bureau of Statistics, Industrial Research-Development Expenditures in Canada, 1959, April, 1961, pp.21-22.

products (this group includes pharmaceutical manufacturing), the percentage is 1.54. The only figures which exceed that for chemicals are 1.81 per cent for electrical apparatus and supplies and 1.90 per cent for transportation equipment. The figure for ethical drug manufacturing given in the above quotation is 6.3 per cent. In all cases research done outside of Canada on behalf of Canadian subsidiaries is included.

4. Contribution of Commercial Firms to Fundamental Research

According to the evidence before the Commission, some drug firms take part in or give financial support to pure and fundamental research. Some examples of such assistance were given by Dr. C. H. Best, Director, The Banting and Best Department of Medical Research and Head of the Department of Physiology, Faculty of Medicine, University of Toronto. Dr. Best said that the Ciba Company of Switzerland, which has branches in many countries, including Canada, established the Ciba Foundation in London, England, to disseminate medical and chemical knowledge. The work of the Ciba Foundation is directed by an independent board on which Dr. Best is one of the members from Canada. Dr. Best mentioned that the work of the Macy Foundation in the United States is directed along similar lines. A second way in which drug firms assist medical research is through grants for the construction of research buildings at universities and other institutions. Dr. Best said that the University of Toronto had received a substantial contribution for such a purpose from the Wellcome Foundation of England, which is supported by the pharmaceutical firm of Burroughs, Wellcome and Company. At an earlier stage Eli Lilly and Company made a substantial grant toward the construction of the research building at the University of Toronto and the same company also made great contributions to the knowledge of methods for making insulin. A further way in which drug firms assist medical research is by providing funds for current research work. Dr. Best said that, if his department is interested in pursuing a certain line of research proposed by a drug firm, such grants are accepted as long as no conditions are attached and he thought that the University of Toronto, at the time of his appearance before the Commission, was in receipt of grants from five or six drug firms (Hearing, pp.2718-22). Dr. Best said that while drug companies would naturally conduct research which would be in their own interest, he knew of many instances where the research work involved a great deal of fundamental research, the results of which were published and thus became generally available (Hearing, pp.2728-29).

Mr. K. Antoft, President, Nordic Biochemicals Limited, read from his Company's brief with respect to the assistance which his firm gives to medical research:

". . . The philosophy of research which we follow is to permit as much scope as possible to our technical personnel in developing their ideas, improving their professional techniques, and in encouraging original and creative thinking. It is a fallacy to assume that productive research can only be carried out through the much publicized 'crash programs', involving armies of technicians and batteries of complex gadgets and computers. On the contrary, it need hardly be pointed out that many of man's most fruitful discoveries have been made by individuals whose thinking was sharpened by the need to improvise and 'make do' with a minimum of resources. In the field of fundamental research, commercial size in itself may often be a handicap. The need to seek approval for each step from management committees is likely to lead to stagnation in this area.

It has been the aim of our company to allow our personnel the greatest possible latitude in designing and carrying out original research, supporting them as much as our limited resources permits. As a result, our company is well known in North American medical research centres as a source of several research materials, and also a place to which investigators may turn for aid in developing techniques or in translating laboratory procedures into production methods. A review of projects that we have undertaken or have participated in would demonstrate that the commercial motive is secondary in most of these endeavours. However, the list is long and filled with 'blind alleys' and therefore only a few pertinent examples will be given here.

1. Our company has undertaken the extraction of various glandular tissues, for the purpose of assisting investigators exploring the physiology and biochemistry of the human body. We have made extracts of pineal glands, diencephalon, the thymus gland, blood, and other tissues, and have made these extracts available without charge to a large number of people working in various Canadian research centres.

2. Human Growth Hormone Project. - Since the existence of pituitary growth hormone was first demonstrated early in the 1940's, many trials had been made with a view to reproducing in man the effects observed in animals from the administration of this hormone. Although many investigators were involved in this research work, the hormone made from animal sources remained without effect when given to man. In 1958, a group of investigators at Harvard University demonstrated that the hormone extracted from monkey pituitaries had a significant effect when injected back into the same species. After this was reported, Dr. John Beck, of the University Clinic at the

Royal Victoria Hospital in Montreal, asked us to set up a collection of monkey pituitaries from animals being used in the Salk vaccine program. Although we secured the complete cooperation of the University of Montreal's poliomyelitis vaccine laboratory, the collection of these pituitaries proved to be very cumbersome. It soon became apparent that it would take several years to collect sufficient monkey pituitaries to make extraction worthwhile. Therefore, we began to collect human pituitaries from autopsy cases, in order to test the theory that growth hormone was species specific in man.* As a result, Dr. Beck became the first clinician to use human growth hormone in a human patient, and he demonstrated that its activity paralleled the results expected from animal experiments. His work has set off a wave of interest in this field, and while the collection of human pituitaries has now become standard practice throughout the world, the initial idea remains a Canadian one. Our company continues to collect pituitaries from pathologists at the major hospitals throughout Canada, extracting the human growth hormone from these. Due to its extreme shortage, the available supply is allocated through the Canadian Society for Clinical Investigation, and we administer this program solely at our own expense. It is obvious that until another source of starting material is found, this project is purely a research undertaking which is unlikely to have any commercial significance.

3. Miscellaneous pituitary hormone fractions. - With the great interest in pituitary physiology, there is a constant demand for various pituitary hormones, as well as for fractions that have not yet been identified as hormones. We offer a nearly complete range of all the known pituitary hormones. In addition, we continually make various fractions whose hormonal action has not yet been characterized. In some instances, we have supplied starting material from which research workers carry out further fractionation. As examples, two of the substances that are currently of interest to us are the 'fat mobilizing' factor from the pituitary, and the factor in the pineal gland area which appears to influence fluid retention.

In most cases we supply these research preparations without charge. If we do not make a particular pituitary hormone ourselves, we may purchase the fraction from one of the members

* The credit for this original idea actually belongs to one of our detail men, Mr. William Levain, who also was active in making arrangements with Pathology Departments throughout Montreal.

of our Scandinavian research pool. These are imported by us at our own cost and distributed, in most cases, without charge to the interested research group."

(Nordic brief, pp.4-7; Hearing, pp.1388-92)

On the support of medical research by Canadian pharmaceutical manufacturing companies, the brief of the Canadian Pharmaceutical Manufacturers Association stated:

"... Some of our companies already have extensive research laboratories in this country, and this has given Canada a good foothold in pure and applied research. And at least one of these commercial laboratories is among the largest research establishments in Canada and is devoted solely to the field of pharmaceuticals.

Other pharmaceutical companies, particularly subsidiaries of foreign research houses, are commencing to build up pharmaceutical research laboratories in their Canadian operations. Still others are contributing experience and finances to our independent researchers and universities.

As evidence of the significance of this assistance, we are attaching to this submission under Appendix E, a list of 158 research studies and fellowships published in the Canadian Medical Association Journal between January 1958 and June 1961, which were supported by pharmaceutical manufacturers. Furthermore, this list does not contain mention of all studies and fellowships supported by pharmaceutical manufacturing during that period. At best it is merely a partial list appearing in one journal.

Clinical investigation in Canada has had a significant growth over the past seven years, particularly in respect to subsidiaries of foreign companies. As you know, this is the final stage of a research project where the new product is studied in humans under controlled supervision after leaving the laboratory and before being placed on the market. As recently as 1954, only a limited amount of clinical research was being done in this country. Since then the amount has mushroomed to the point where today the clinical trials for a new product are usually carried on in Canada simultaneously with the trials being conducted in the country of origin. The contribution of Canadian medicine in the clinical evaluation of drugs is now widely recognized.

The clinical investigation stage of research and development usually comes under the aegis of a company's medical director. The medical director, in addition to his liaison with the medical profession, devotes a large portion of his time to initiating and supervising various clinical investigations to evaluate potential new drugs. He is also required to check all medical literature and other promotional material before release. His role in the industry covers a wide area, and he must keep himself constantly up-to-date on all new forms of treatment and on the changes taking place in the practice of medicine. Together, these medical directors constitute a specialized group of physicians. They have their own section with C.P.M.A. which, in turn, is affiliated with the Canadian Medical Association."

(Association brief, pp.35-36; Hearing, pp.1887-89)

Appendix E to the C.Ph.M.A. brief referred to above lists approximately 160 studies. In the majority of instances it appears that the support consisted in the supply of drugs to the investigators. Other forms of support were: "grants", prizes to general practitioners, collaboration in symposia, grant of money for a floating research laboratory, fellowships, scholarships, and grants-in-aid.

5. The Relation of the Size of Firm to
Fundamental Research

The Director, in his description of small ethical drug firms, made certain observations including the following:

"... they carry on little or no research, they are not able to develop new drugs or important specialties and they are unable to carry on elaborate promotional campaigns. The products which they do sell may be of high quality, indeed some have usually been purchased from the large ethical drug houses and are identical with those sold by the latter, but the small firms do not enjoy the same reputation as the large firms."

(Green Book, p.61)

At the hearing held in Montreal, exception was taken to this remark by Mr. K. Antoft, President of Nordic Biochemicals Limited, who was convinced that size has no direct relationship to achievement in the field of research. He referred to his own company's successful efforts to improve processes for the manufacture of ACTH (Corticotropin and Corticotropin, type A), which made large-scale processing practicable

and also greatly increased both the potency and purity of the drug and the duration of its effective action, together with rapidly declining costs of production. His company manufactures Corticotropin completely in its own plant in Montreal.

Mr. Antoft also mentioned other research activities of his company. Some of his company's research products had benefited greatly from the company's association with certain European companies in Denmark and Sweden. Others had been conducted entirely by his own company in Canada (Hearing, pp.1386-89; 1393-94; 1428-30).

While he could speak only for his own company, he felt that other small companies, if they had seen the Director's statement, would be moved to make similar comments (Hearing, p.1411).

It should be noted that at the last hearing in Ottawa the Director's representative made the following statement:

"MR. MACLEOD: . . . on page 61 [of the Green Book] you will recall that the manager of Nordic Drugs in Montreal took some exception to our definition of 'small ethical drug houses'. He thought it was a bit too sweeping, and possibly he is right. The information obtained by the Director from many small firms led him to believe this was the correct situation, but if the definition has to be modified in the light of Mr. Antoft's information, we can agree to it being so modified."

(Hearing, p.3084)

6. The Importance of Research to the Profitability of Drug Firms

The Green Book (para.217, p.137) quoted from an article in Fortune, May 1960, to the effect that research expenditures were a primary factor in determining a drug company's future share of industry sales, that increasing its share of industry research outlays almost invariably gave a drug company a higher share of the market, but that when every firm used research as a competitive weapon to improve its market position, increased expenditures upon research ceased to be as effective as formerly. This article mentions the advantages accruing to the firm which first brings a new drug to the market. These statements from Fortune were made with reference to drug manufacturing companies in the United States.

An important advantage accruing to the innovating drug manufacturer appears to be the loyalty of doctors to a particular manufacturer's brand of a new drug. On this subject Mr. R. B. Thompson, Manager, Medical Products Department, Cyanamid of Canada Limited, testified as follows:

"MR. MACLEOD: There was one small point I wanted to clear up. You said this morning that, taking Tetracycline as an example, that there would be differences in the products of various manufacturers. That is one might use a different type of capsule or different excipients, something of that nature?

MR. THOMPSON: Yes, there is no standard that requires identity in formulation. That is correct.

MR. MACLEOD: In practice does this lead to a doctor using, for example, your brand of Tetracycline in one instance and say Squibb's brand for instance in another or does the doctor normally when he wants Tetracycline use one brand?

MR. THOMPSON: It is rather an interesting comparison that you have picked because according to the information I have the Squibb Company markets Tetracycline only in combination with an agent calculated to reduce the incidence of overgrowing fungus infection that develops.

MR. MACLEOD: Let's take Pfizer. Take Pfizer.

MR. THOMPSON: There is a strong brand loyalty. At least we have experienced that in our own company. We have found that physicians who have used Achromycin are very well satisfied and tend to continue to use it. It's a little difficult for me to speak of a competitor, but I can say that the physician who is using my product is visited regularly by Pfizer people who always have good reasons why he should change away from my product to Pfizer's.

MR. MACLEOD: But you find that there is a certain amount of brand loyalty?

MR. THOMPSON: Yes, and I contribute [sic, attribute] it to some degree at least to the reputation that we have sought to build for our company. We would like physicians to have confidence in a product simply because it comes from our company. That is one of our objectives: the way we conduct ourselves.

MR. MACLEOD: The point I wanted to clear up, I was

quite sure of it in my own mind but I wanted to get it on the record that when you spoke about the difference you didn't mean that in practice the doctor uses your drug today and somebody else's product tomorrow?

MR. THOMPSON: No, I didn't mean that. I beg your pardon, in the case of Tetracycline capsules I think the physician acquires experience with a particular make of Tetracycline, particular brand, and he becomes accustomed to the pattern of response and then his inclination is to continue to use it simply because it is a familiar pattern to him. There is a reluctance to switch because of the possibility that he may have to become accustomed to a different pattern."

(Hearing, pp.1724-25)

With respect to the role of research, the tapering off in discoveries, and the losses which companies sustain on research failures, the brief of the Canadian Pharmaceutical Manufacturers Association stated:

"While Canada's pharmaceutical manufacturing industry was born in the middle 1800's, it did not gain a measurable economic stature until the post World War II years. It is within this past two-and-a-half decades, and the last one in particular, that pharmaceutical manufacturing has undergone a transition unprecedented in its history.

. . .

Companies such as Lederle, Parke Davis and Pfizer which had introduced Aureomycin, Chloromycetin and Terramycin respectively, were entering a new period of development and growth. Wholly-owned Canadian companies such as Frosst and Horner, were also investing their reserves in research facilities to maintain their positions in the market, on the premise that no company can hope to survive without access to research.

The boom in growth produced economic hazards for the companies which were only coming to learn that theirs was a risk industry. New discoveries were rewarding, but the cost of research and development was high. Lilly lost \$850,000 on but one research failure, while SKF underwrote \$750,000 on another. In 1958 alone, the pharmaceutical industry in North America worked on 114,600 different chemical substances in its laboratories. Less than 40 reached the market.

Still the North American market for pharmaceuticals grew. Upjohn built a new manufacturing plant at Don Mills, Parke Davis built at Brockville and Pfizer at Arnprior. Hoechst opened a Canadian company to handle its then revolutionary oral anti-diabetic. Ortho built at Don Mills, while Ciba and Sandoz moved to larger facilities at Dorval. Wyeth at Windsor and BDH at Toronto made extensive plant additions. Other established companies followed suit, and still newer firms entered the Canadian market, adding to employment and the Canadian economy.

Competition via discovery became stiff. Formerly a leader in the corticosteroid market, Schering's earnings on this continent suddenly dropped 23 per cent in two years, when three other major competitors entered the field. The price of penicillin on the world market had become so low, that companies in Canada stopped producing the raw substance. Merck was forced to close its multi-million dollar penicillin, streptomycin and cortisone plant outside Montreal, as a result of imports from low cost countries, and some 400 Canadians were out of jobs. As a result of competition at the manufacturers' level, reserpine underwent a drastic drop in price within 18 months of its introduction to the Canadian market.

At the end of its second decade of rapid development, the industry's phenomenal growth is levelling off. Research is not producing as many new discoveries, and the companies are placing more and more money into research with the hope of breaking the barrier to still another new molecular substance which, in turn, will produce a further upsurge in growth. Allied to this is the development of new drugs to compete with other drugs which, although different in content, are used for the same medical purpose."

(Association brief, pp.3-5; Hearing, pp.1798-1800)

Questions with respect to research failures brought out the following answers from Mr. S. N. Conder, General Manager of the Association:

"THE CHAIRMAN: Are you speaking now of the United States or Canada?

MR. CONDER: No. This would be based on the North American operations of the company.

THE CHAIRMAN: Can you give us the source of this information?

MR. CONDER: Oh, I am sorry, sir. Yes. Regarding the Lilly project, this covered a 15 month clinical survey on Carbutamide a Sulfanilamide derivative for the treatment of diabetes. This clinical study turned up so many side effects that Lilly abandoned the project.

THE CHAIRMAN: You got that information from Lilly did you?

MR. CONDER: Yes sir, that is correct. Now the one under the S.K.F., this was a new product to prevent vomiting and to control psychosis. As 100 Internists pronounced this new remedy 'excellent' S.K.F. decided, however, that this product was not significantly better than others on the market, and it was not completely free of side effects. This is another example of why the decision not to market a drug can be costly.

MR. FRAWLEY: Is this the Canadian S.K.F. or the U.S. S.K.F.?

MR. CONDER: This is the U.S. S.K.F., Mr. Frawley.

. . .

THE CHAIRMAN: When you say less than 40 reached the market, do you mean reached the market in 1958 or have ever reached the market?

MR. CONDER: Have ever reached the market, yes sir."

(Hearing, pp.1800-01)

"MR. MACLEOD: Page 31, Mr. Conder, you have a statement on the high degree of risk in the industry. Up to the present hasn't that been more theoretical than real? Hasn't the fact been that a greater majority of companies have been able to bring out new products, successful products? There are many examples of that. Now I suggest to you there are very few examples of a company failing or suffering substantial loss because of its product going out of fashion.

MR. CONDER: I understand, Mr. MacLeod, that there have been many examples of products which have been replaced to one degree or another over the years. That is the point on risk that is mentioned or used in our brief. . . . "

(Hearing, p.2168)

From the evidence quoted above, Mr. Conder appears to be saying that the research failures result from the displacement of one chemical by another rather than from the danger that companies will suffer substantial losses in their overall operations.

Dr. C. H. Best, Director, The Banting and Best Department of Medical Research and Head of the Department of Physiology, Faculty of Medicine, University of Toronto, testified as follows on the supposed slowing-down in the rate of discovery of new drugs:

"MR. WHITELEY: We have also had some suggestion that in the last ten years there has been sort of a burst in the results of research that result in a great range of new products of very superior efficacy, and that burst may have sort of tapered off recently.

DR. BEST: Well, history is a series of bursts, I think, with little lulls in between.

The Department of Pharmacology in the Universities, at least some years ago, had a little trouble finding enough to talk about and do research on. Now, as far as I know, all across the country the Departments of Pharmacology are increasing in number all sorts of new things for them to teach students about. It is one of those eras where you can say there has been a great burst of activity in pharmacology.

THE CHAIRMAN: I think what Mr. Whiteley was referring to is the sort of idea that you get a break that leads to a lot of research with several lines arising out of that.

DR. BEST: Yes.

THE CHAIRMAN: Then there may be a quieter period. From your experience would you say we are getting a good many of these breaks and there is no sign of disappearing?

DR. BEST: I try to keep track of the number of papers on insulin over the years. I think there have been about 90,000 since our first publication, and there is just as much activity in the world today -- seven new papers on insulin every day. That has gone in waves, you know. There has been a lull and then something has happened, and a lot of people get interested; particularly in relation to these drugs which affect brain cells there has been a tremendous outburst of activity now, and I hope indirectly that will pay off by having fewer inmates in some of these institutions."

7. Medical Research and the Development of Patents

A question of some interest is whether or to what extent the profit motive is necessary to progress in medical and drug fields. Dr. L.B. Pett, Principal Medical Officer for Research Development, Department of National Health and Welfare, was asked about the origin of a number of major contributions to medical science which have been developed in Canada and which were listed in the Farquharson Report⁽¹⁾. Dr. Pett referred in his evidence to the discovery of insulin at the University of Toronto but pointed out that some of the developments listed involved medical or surgical procedures rather than drugs. His evidence included the following:

"DR.PETT: The work I am familiar with was done in teaching hospitals, that means hospitals associated with universities and therefore closely allied [with them] rather than with drug firms. But I would not like to suggest that there isn't an aspect which was necessary for the research here that would come only from a drug firm. I am referring specifically to the ability of a drug manufacturer, used in a general sense, to prepare a product such as a hormone which has to be extracted from animal tissue on a fairly large scale. This cannot generally be done in a university lab, it requires larger facilities, and I shouldn't be surprised to find, delving into these, that there was involved in some of them, certainly in the hormones, such assistance by drug firms. "

(Hearing, 230-31)

Dr. C. H. Best, Director, The Banting and Best Department of Medical Research and Head of the Department of Physiology, Faculty of Medicine, University of Toronto, said that the practice of the institutions he has been connected with in regard to patents has varied over the years. Dr. Best said he was speaking as a professor of medicine and not as a manufacturer to whom he supposed that patents would be valuable. When insulin was first discovered a patent was secured which was transferred to the University of Toronto for one dollar. The University gave away the rights in all countries of the world except the United States, in which it was readily possible to standardize each batch

(1)

Report to the Honourable Gordon Churchill, Chairman, The Committee of the Privy Council on Scientific and Industrial Research, by the Special Committee Appointed to Review Extramural Support of Medical Research by the Government of Canada, November 12, 1959, p.1.

of material by testing in Toronto for which a royalty or testing fee was charged. Dr. Best mentioned some later discoveries at the University of Toronto for which no patents were taken out (Hearing, pp.2722-24; 2725-26).

On the subject of the relation between a particular Canadian drug firm's expenditures on research and its sales volume, the Director says:

" . . . Generally, those firms which spent the most on research in an absolute sense also spent the most relative to sales. However, there were a few exceptions and, in one instance in particular, a firm having somewhat smaller sales than the larger firms reported as high a relative expenditure on research. On the basis of the information supplied by the selected firms, there appears to be no correlation between the rates of profit of particular firms and their expenditures on research."

(Green Book, pp.128-30)

It is doubtful whether a positive correlation should be expected to arise from data for a single year. Such a correlation might be observed only if the data had been available on the total sales and expenditures for a considerable period of years.

8. Relative Proportions of Research carried on
Within and Without Canada

While some important developments in connection with drugs have originated in Canada or have been significantly aided by research in Canada, it is clear that most of the research done by the large ethical drug firms with Canadian subsidiaries is carried on outside Canada, in the United States or elsewhere. The Director notes that the antibiotics and tranquillizers were developed outside of Canada (Green Book, p.2). In addition he makes the following observations:

"220. . . . The question which is posed by this article [1] when the observations made are applied to the Canadian industry is whether it is possible for a Canadian industry to be developed independently of American industry or whether it is inevitable that the Canadian industry will be entirely dominated by the

[1] Charles E. Silverman, "Drugs: The Pace is Getting Furious", Fortune Magazine, May 1960, pp.138-41, 269-70, 275-76 and 281-82.

competitive situation in the United States. As an example of the dominant influence the United States can be expected to have in the drug industry, it is interesting to note that Lederle Division of Cyanamid with sales in 1959 estimated at \$160 million (approximately 7 per cent of sales of the industry of \$2.3 billion) is estimated (using figures from the Fortune article) to have spent \$12 to \$16 million on research and to compare this with the total expenditure on research of \$2.0 million reported by the twenty-two Canadian firms listed in Table XXVII. In other words, a single firm in the United States spent approximately six to eight times as much on research as did twenty-two Canadian firms which include the largest in the field in Canada. For the particular firm, Cyanamid, the contrast is even greater. For the year 1959, the parent U.S. company spent one million dollars on research for each one hundred dollars spent on research by its Canadian subsidiary.

. . .

222. While the Canadian public derives benefit from research done in other parts of the world, notably the United States, and while Canada has contributed substantially to the general knowledge of disease and its treatment, many authorities in the field feel that more should be done in Canada to support and encourage medical research. While other factors are also pertinent, the relationship of most of the large drug manufacturers to parent or related firms in other countries results in the research for such firms being carried on outside Canada."

(Green Book, p.140)

Mr. R. B. Thompson, Manager, Medical Products Department, Cyanamid of Canada Limited, testified on the benefits to Canada of research done in the United States as follows:

"MR. THOMPSON: . . . Cyanamid's Canadian business has formed part of the North American business of the Cyanamid group. This relationship has brought many advantages to Canada, including particularly the benefits of American research and experience resulting in the rapid introduction of new and tested drugs to the Canadian market."

(Hearing, pp.1536-37)

Some witnesses pointed out that Canada gets the benefit of medical research done all over the world, although in times of shortages of supplies Canada may not receive supplies of new drugs immediately. Dr. L. B. Pett, Principal Medical Officer for Research Development, Department of National Health and Welfare, testified on this matter as follows:

"MR. MACLEOD: Is the nature of the exchange of scientific knowledge such that Canada gets the benefit of research done in any part of the world? If progress is made on a disease in Sweden or Switzerland or the United States, does the knowledge come to Canada?"

DR. PETT: I think it comes pretty rapidly; perhaps less rapidly from behind the Iron Curtain. Even from there there is a constant, I might say, tremendous flow of information comes into Canada from all over the world.

MR. MACLEOD: Are you able to say anything about drugs in that connection? When a new drug is developed in some other country, does it normally become available in Canada within a reasonable time?

DR. PETT: I have no knowledge of this in my personal position. As a physician, not in practice at the moment, sir, I can say we are liable to read of drugs in other countries before they are available in Canada, but just how long a gap there is, I don't know.

MR. MACLEOD: In the normal course of events they do come eventually.

DR. PETT: They do come eventually.

MR. MACLEOD: While there may be some time lag, normal experience is that Canada received the benefit of any new product developed anywhere in the world?

DR. PETT: I would think so.

MR. MACLEOD: I think those are all the questions I have, sir.

THE CHAIRMAN: Just one question arising out of the last question that Mr. MacLeod asked. Perhaps you cannot answer this either. It occurred to me this might be the situation that sometimes a product that is developed overseas, we will say, is confronted with a shortage of materials from which it is made and therefore it is in very short supply. It may take some considerable time to develop

supplies to the point where they can be exported to other countries, such as Canada; whereas in other instances there may not be shortages of that kind. Would that affect the period of time that might elapse.

DR. PETT: Yes, there is no question."

(Hearing, pp.239-41)

Dr. C. H. Best, Director, The Banting and Best Department of Medical Research, and Head of the Department of Physiology, Faculty of Medicine, University of Toronto, testified on this subject as follows:

"MR. MACLEOD: Dr. Best, would you care to express any opinion on the situation with respect to most basic drugs being imported from the point of view of Canada's national security and things like that? For instance, I understand that penicillin is no longer manufactured in Canada.

DR. BEST: Well, we have the know-how certainly to make penicillin in Canada, and it was made here for a long time. I would think that there are at least two groups that are perfectly capable of making penicillin, but if we were in the process of making it, it would take some time to catch up in the case of an emergency. Of course I think in general the more independent, we are, the safer.

MR. MACLEOD: That was the point I was getting at. Do you think a certain amount of manufacture should be carried on here anyway regardless of its cost?

DR. BEST: Well, I have been chairman of the medical committee of the Defence Research Board ever since it was formed, and that question has come up again and again, and I think there would be occasions particularly for materials that would be needed in an emergency where it would be justifiable to subsidize a pilot plant to keep it running in case our supplies from other sources were cut off."

(Hearing, p.2727)

9. Possible Extent of Future Research by Drug Companies in Canada

The Green Book (para.212, pp.130-35) gives the replies of some firms to the Director's inquiries about the type and scope of the research programmes which they carry on in Canada. There appears to be considerably more research done by certain companies, notably Ayerst, Frosst and Horner, than by others ⁽¹⁾ It may be noted that Frosst and Horner also informed the Director that they were not subsidiaries of any other companies. A number of companies do not carry on research programmes in Canada at all. Some companies undertake only clinical research on new products, initiating and supporting such work in the hands of independent physicians and medical institutions. Dr. Roger Gaudry, Director of Research, Ayerst, McKenna & Harrison Limited, testified as follows with regard to the increasing volume of clinical investigation being carried on in Canada:

"DR. GAUDRY: This is in connection with the much rapidly increasing amounts of money for clinical investigation in Canada. I would like to say this, the Food and Drug administration in Ottawa is now requesting that some clinical investigation be done in Canada before accepting new drug applications. This is one of the reasons why a lot more money has to be spent on clinical investigations than used to be the case a few years ago.

THE CHAIRMAN: Do you [know] when the Food and Drug Directorate adopted this requirement?

DR. GAUDRY: Well, I don't believe that they adopted [it], but they completely changed their laws or principles, but they are just requesting more and more frequently that this be done. While a few years ago they accepted applications based almost entirely on work done in the United States and in Europe, now they seem to accept them no more. I am not too sure it is in all the cases, but in most cases they seem to insist work be done in Canada.

THE CHAIRMAN: I am recalling that yesterday we had some evidence that in 1960 there was a very marked step-up in the amount that was being spent on clinical investigation, clinical research. I wonder if that is associated with any increase in the pressure, might I say, put on the companies by the Directorate.

DR. GAUDRY: Well, I think so, or partly, but of course there are more compounds, more new compounds being tested

(1)

Re Horner, see footnote (1), page 59.

clinically and therefore more new compounds in Canada if the companies want to import them in Canada.

THE CHAIRMAN: That is all you wish to say?

DR. GAUDRY: That is all, sir."

(Hearing, pp.1921-22)

An interesting question is whether the amount of pharmaceutical research carried on in Canada by the large drug manufacturing firms will increase in future or not. In the case of Canadian companies which are subsidiaries of foreign companies the issue becomes one of the relative advantages of centralizing or decentralizing research and development. On this subject, the brief of Cyanamid of Canada Limited stated:

"The Canadian consumer purchasing drugs manufactured by a Canadian subsidiary of an American parent company finds that he is contributing to the cost of research whether that research is carried on in Canada or in the United States. In the present state of development in Canada, as has been pointed out, it is more economical at the present time that Cyanamid research be carried on at the already existing facilities of the parent company.

We have no doubt, Mr. Chairman, that as the Canadian pharmaceutical industry expands, so will research activities expand. This is certainly our expectation at our own manufacturing centres in Canada, especially when we are engaged in a full scale manufacture of broad spectrum antibiotics. American Cyanamid Company has indicated its willingness to decentralize its basic research activities. An example of such decentralization is the Geneva Research Laboratory maintained in Switzerland by American Cyanamid. As research efforts in the industry become increasingly directed toward fundamental research, it becomes increasingly possible to decentralize."

(Cyanamid brief, p.45; Hearing, p.1532)

Mr. R. B. Thompson, of Cyanamid, further testified as follows:

"MR. WAHN: In your evidence you have said that up to the present time there has been -- that research in Canada in this particular field has been somewhat limited. Is there any

reason to think that must necessarily continue in the future, or is there any chance of increased research in Canada in this field?

MR. THOMPSON: No, I think there is every hope that research activities will develop in Canada. We have excellent people here. We have excellent academic centres where we do have some research. The Ayerst Company has an excellent pharmaceutical research set-up in Canada. So has the Charles Frosst Company, and to some extent so also has the Frank Horner Company.

I believe this is just the beginning. These are merely beginnings, but they reflect the confidence that these companies have in the talent that is available, and, as I think I said in my comments, it is becoming increasingly necessary for the mountain to come to Mohammed, Mohammed being the technically trained people.

I think if research is a world wide effort, in our company it is not all done in the United States, and I believe it will become increasingly decentralized so as to take the best advantage of all the skills and talents available all over the world, and I think Canada is one of the best candidates for that.

THE CHAIRMAN: Do you think that there are no over-balancing advantages in concentration of research?

MR. THOMPSON: Well, research occurs at several levels, Mr. Chairman. You have the pure research, for example, the technique of tissue culture which made possible the Salk vaccine and development.

The technique of tissue culture is a science which had to be understood and developed before it could be used for the production of any vaccine. This, if you like, is fundamental research, not done for the specific purpose of making Salk vaccine, but in the hope that it would have some application as a fundamental form of research. Much work was done in this very field right in Canada by the Connaught Laboratories. So that there are elements of research that I believe can very well be decentralized into a country like Canada.

I think there are others where the centralization of facilities is a big advantage. Pilot plant operations where you make your first small amount of a new drug, can perhaps best be associated with a large production unit where the know-how can be traded back and forth.

The research in the pharmaceutical industry is becoming increasingly basic. It is increasingly a thing which can be done in university teaching centres, under grants, and where decentralization I think is not only practical but necessary. There are just not enough trained people."

(Hearing, pp.1568-70)

"MR. HUME: . . . Then, on the question of research, I take it from your evidence, Mr. Thompson, that while there is as you point out a relatively small amount of research being actually done in Canada, would it be your opinion that Canadians are paying their own way in research?

MR. THOMPSON: Yes.

MR. HUME: That is to say, we are benefiting by research done in other countries, in other parts of the world, but we are paying for that in the cost of the products that we either import or obtain by some arrangement that the companies have, is that right?

MR. THOMPSON: Very, very definitely.

MR. HUME: So when a Canadian produced product is sold where research is done in the United States, part of the cost of the product in the Canadian company is an element of research in the other parts of the world?

MR. THOMPSON: Yes, and that amounts to 9.6 per cent of sales."

(Hearing, p.1575)

Dr. C. H. Best, Director of The Banting and Best Department of Medical Research and Head of the Department of Physiology at the University of Toronto, testified on this matter as follows:

"THE CHAIRMAN: Apart from the Institutes which you have been connected with, it seems to be the case that a great majority of research in the field of drugs has been carried on with respect to Canada by their parent companies elsewhere, largely in the United States. We have been told that that is likely to change, or perhaps it is even beginning to change. I wonder if your experience indicates any noticeable change in that direction.

DR. BEST: Yes. Without giving and without being able to give you any figures, I would think that the volume and the importance of research by these subsidiary companies in Canada is increasing. There are some good examples of accomplishments that they have made in Canada.

THE CHAIRMAN: By using skills which are developing in Canada, the total effect should be greater?

DR. BEST: Yes, I would think so."

(Hearing, pp.2727-28)

The brief presented on behalf of Nordic Biochemicals Ltd. by its President Mr. K. Antoft contains the following recommendations aiming at the encouragement of research:

"... The only basis for any sound industry, however, is in the development of new ideas and new products. This requires that existing Canadian industries devote more of their resources towards both basic and applied research.

On the part of the government, such objectives could be encouraged by permitting bodies such as the National Research Council to work more closely with industry. The United States example of the National Institutes of Health's Cancer Screening program is one method in which this could be accomplished. Under this program, research and development contracts are farmed out to private pharmaceutical companies, and promising results have already developed from this approach.

Many of the medical research programs that are now being carried out at universities could well be broadened to enlist the cooperation of pharmaceutical research laboratories. In this way, incentive would be given to scientists to enter Canadian industry and thus enlarge the horizon of Canadian manufacturers. Our position is weak in competing in mass production, but this deficiency could certainly be overcome by employing more inventive genius."

(Nordic brief, pp.17-18; Hearing, pp.1408-09)

CHAPTER VI

PATENTS

1. Patents on Drugs

In a few countries including the United States and Great Britain, drugs, and also the processes of their manufacturers, may be patented. On the contrary, in Italy, ". . . all kinds of medicines and processes for the production thereof" have been held to be unpatentable.⁽¹⁾ Midway between these extreme positions stand a number of countries including Canada, where processes for the manufacture of drugs are patentable, but not the drugs themselves when made by chemical processes (Green Book, pp. 40-42; Appendix E to this Report, Patent Act, s. 41(1)).

The annual reports of the Commissioner of Patents contain statistics on the number of patents issued, the nationality of the grantees and the country of residence of the inventors. For the year ended March 31, 1961, 22,014 patents were granted for all purposes. Of this total, 2,036 or 9.2 per cent were issued to Canadian citizens or companies and 19,978 or 90.7 per cent to applicants of foreign origin. The place of residence of the inventor was the United States in the case of 15,014 patents (68.2 per cent of the total); the United Kingdom in the case of 2,286 (10.4 per cent) and Canada in the case of only 1,258 (5.7 per cent)⁽²⁾. In the opinion of the Commissioner, Mr. J.W.T. Michel, the percentage for Canadian inventors would be even smaller with respect to patents on drugs. In his evidence, he explained this phenomenon as follows:

In the opinion of the Commissioner of Patents one reason for the high proportion in Canada of patent applications from foreign residents is that Canada is regarded as a progressive country with a great future in industrialization. This leads inventors from many countries to file applications for patents in Canada as soon as they have filed in their home countries. Other industrialized countries of comparable size to Canada have a very great number of patent applications from foreign residents (Hearing, p. 311).

(1) Wm. Wallace White and Byfleet G. Ravenscroft, Patents Throughout the World, 2nd Edition, 1959, p. 204.

(2) Report of the Commissioner of Patents for the year ended March 31, 1961, pp. 9, 12 and 13.

Information assembled by the Director with respect to the patents on antibiotics and tranquillizers show that a very small proportion is held by Canadian residents. A return reproduced in the Green Book (pp. 33-38) and compiled by the Patent Office in answer to a question asked in the House of Commons on February 24, 1960 indicates the country of residence of the holder of any patent issued with respect to 11 antibiotics including penicillin, streptomycin, dihydrostreptomycin and the broad spectrum antibiotics chloramphenicol, tetracycline, chlortetracycline and oxytetracycline. According to this return, out of 372 patents - (the total number of patents on antibiotics was estimated by the Commissioner of Patents to be around 500 (Hearing, p. 303)) - 313 are held by residents of the United States and only nine by Canadian residents. With respect to tranquillizers, of the seven Canadian patents that had been reported to the Director in 1958, six were held by foreign firms (Green Book, pp. 55-56). The seventh had also been issued to a foreign firm but subsequently assigned to its Canadian subsidiary.

While defending the standard of Canadian patents with regard to their validity, Mr. J. W. T. Michel, the Commissioner of Patents, stated that a high proportion of the patents that are contested are invalidated by the courts and that this proportion is greater with respect to patents on drug manufacturing processes than to patents in other fields. He said that he did not regard the high proportion of patents which are declared invalid when contested in court as indicative of the standards applied in the granting of patents because in his view, only the patents open to challenge become the subject of court action. He went on to express the opinion that a higher proportion of patents with respect to drugs might be found invalid by the courts than would be the case with patents generally. This would be due, he said, to the fact that a patent is obtainable only on the process of manufacture of the drug and the patent examiner might be more lenient than would be the case if a patent could be obtained on the product itself (Hearing, pp. 306-07).

It was pointed out to the Commission that often it is very difficult to determine whether or not two drugs have been made by the same process. In this respect, the brief of Cyanamid of Canada Limited stated:

"... Canada recognizes only process patents (not product patents), so that drugs may legally be manufactured or imported, and sold in Canada, when they have been manufactured by a process different from that which is the subject of the Canadian patent. This is precisely what is being done in Canada today. Quite a large number of importers are marketing drugs in Canada which may or may not be infringements of Canadian patents, and they pay no royalties. These people are being encouraged

by the purchasing agencies of the government, hospitals and others who buy from them."

(Cyanamid brief, p. 42; Hearing, p. 1524)

With respect to the above quotation, Mr. R.B. Thompson, of Cyanamid, gave the following evidence:

"THE CHAIRMAN: Mr. Thompson that would suggest there might be a great deal of difficulty in finding whether they are infringing the Canadian patents. Is that the case?

MR. THOMPSON: Yes Mr. Chairman. This can be exceedingly difficult. Only in limited situations can we determine by analysis the process by which a drug has been produced. More frequently it is impossible to tell.

THE CHAIRMAN: Unless you had access to their plants, I suppose you ---

MR. THOMPSON: Yes.

THE CHAIRMAN: --- find it very, very difficult."

(Hearing, pp. 1524-25)

Because of the difficulty of establishing whether or not two drugs have been made by the same process, section 41(2) of the Patent Act (see Appendix E) puts the onus probandi on the shoulders of the defendant in an infringement suit. This may make some manufacturers more ready to take proceedings when they believe that their patents are being infringed either by manufacture in Canada or by importations. Actually some patent holders take advantage of this provision, for, according to information submitted by Mr. F.R. Hume, counsel for the Canadian Pharmaceutical Manufacturers Association, there are presently sub judice before the Exchequer Court four, five or six cases in which it is alleged that goods have been imported in contravention of the Patent Act (Hearing, p. 1993).

2. Compulsory Licensing

In Canada, there are provisions for compulsory licensing on grounds applicable to patents in all fields. Under section 30 of the Combines Investigation Act (see Appendix A), the Exchequer Court of Canada may direct the grant of licences, whenever a patent has been used to restrain or injure trade unduly. Under section 67 of the

Patent Act, compulsory licences may be issued, whenever there has been an abuse of exclusive rights under a patent. Such exclusive rights are deemed to have been abused, among other circumstances, when, after the expiration of three years from the date of issuance of a patent, the public demand for the patented article is not being met to an adequate extent and on reasonable terms or the patented invention, without justification, is not yet being worked within Canada on a commercial scale. In addition to these provisions of general application, section 41(3) of the Patent Act (see Appendix E) provides specifically for the compulsory licensing of patents relating to food and drugs. Enacted in the interest of public health, this provision weakens considerably the monopoly rights ordinarily granted under patents.

From the decisions rendered by the Commissioner of Patents and also by the courts, it appears that section 41(3) has been given a broad application. In Charles E. Frosst & Co. v. Carter Products Inc.⁽¹⁾, the Commissioner took the view that the sub-section does not exclude from ready access or availability to the public substances that can be obtained by processes that are not chemical or that "could later (after the grant of the patent) be found to be useful for food or medicine or capable of being used in the preparation of food or medicine". In Gilbert Surgical Supply Co. Ltd. v. Parke, Davis & Co.⁽²⁾, the Commissioner reached the conclusion that section 41 "does not differentiate between process or product patents in so far as licensing is concerned". This finding remained unmodified on appeal to the Exchequer Court⁽³⁾. Moreover, according to a decision rendered by the Supreme Court of Canada in Parke, Davis & Co. v. Fine Chemicals of Canada Ltd.⁽⁴⁾, the word "medicine" includes the bulk product and section 41(3) applies to products as well as to processes. However, with respect to the latter finding, it should be noted that in this case both process and product were involved and the Court did not specifically discuss the situation where only a product claim might be made⁽⁵⁾.

(1) 29 Canadian Patent Reporter 145.

(2) 30 Canadian Patent Reporter 21.

(3) 30 Canadian Patent Reporter 55.

(4) 30 Canadian Patent Reporter 59.

(5) For a discussion of these decisions, see Peter Kirby, "A Decade of Decisions on Food and Medicine Licences (1951-1961)", 36 Canadian Patent Reporter 15.

3. Conditions of Issuance of Compulsory
Licences under Section 41(3)

Under Section 5 of the International Convention for the Protection of Industrial Property⁽¹⁾, three years must elapse after the grant of a patent before an application for a compulsory license may be made. However, it was decided by the Commissioner of Patents⁽²⁾ and also by a British Court⁽³⁾ that this provision deals only with situations where abuse of privileges is a prerequisite for a compulsory licence. Accordingly, the granting of a licence under section 41(3) immediately after the issuance of the patent does not constitute a violation of the International Convention.

Moreover, the Commissioner of Patents, unless he can see "good reason to the contrary", must grant the licence subject to the payment of a royalty. In his own words:

"The Commissioner has to make a proper investigation which may consist in part in a hearing of the parties. If his findings are that the petitioner is qualified to work the patent, that he has a reasonably permanent organization, that the Canadian market is not already over-supplied with the product of the patent and that the public interest will benefit or at least will not suffer, then there is no alternative but to grant the licence."⁽⁴⁾

(1) The text of this convention, to which Canada is a party, was adopted at Paris in 1883 and modified at Brussels in 1900, at Washington in 1911, at The Hague in 1925 and at London in 1954. Another revision took place at Lisbon in 1958, but Canada has not yet signed the Lisbon Convention.

(2) Frank W. Horner Ltd. v. Sharp & Dohme (Can.) Ltd., 15 Canadian Patent Reporter 68.

(3) Parke, Davis & Co. v. Comptroller General of Patents, "Designs and Trade Marks and Others, 1954", All E.R., Vol. 1, pp. 671-76.

(4) Frank W. Horner Ltd. v. Sharp & Dohme (Can.) Ltd., 15 Canadian Patent Reporter 68, at p. 70.

In short, the patentee has the onus of showing to the satisfaction of the Commissioner that the public interest would suffer from the grant of the licence. Up to now, this onus, in almost all instances, has not been discharged in a way which would lead the Commissioner to refuse a compulsory licence. The Commissioner has not yet been convinced that an applicant was not qualified either financially or professionally,⁽¹⁾ and he has rejected all arguments to the effect that the applicant had previously infringed the patent⁽²⁾ or could not produce economically in commercial quantities⁽³⁾ or that the market was already adequately supplied⁽⁴⁾. In this respect, the Commissioner of Patents gave the following evidence to the Commission:

"Reasons to the contrary being such as the patentee already manufacturing in Canada, public demand being fully supplied, prices being reasonable, the applicant intending to produce only the bulk material leaving to others the tableting, capsuling, compounding, etc., have all been rejected by the Commissioner of Patents in Canada and by the Comptroller General in the United Kingdom (where the law is similar to ours) and the courts have concurred where appeals have been made."

(Hearing, p. 295)

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- (1) Frank W. Horner Ltd. v. Sharp & Dohme (Can.) Ltd., 15 Canadian Patent Reporter 68; Delmar Chemicals Ltd. v. American Cyanamid Co., 32 Canadian Patent Reporter 40; Micro Chemicals Ltd. v. Societe des Usines Chimiques Rhone-Poulenc, 37 Canadian Patent Reporter 93.
 - (2) Parke, Davis & Co. v. Fine Chemicals of Canada Ltd., 30 Canadian Patent Reporter, at pp. 65-67.
 - (3) Delmar Chemicals Ltd. v. American Cyanamid Co., 32 Canadian Patent Reporter 40.
 - (4) Parke, Davis & Co. v. Fine Chemicals of Canada Ltd., 30 Canadian Patent Reporter, at pp. 65-67; Delmar Chemicals Ltd. v. American Cyanamid Co., 32 Canadian Patent Reporter 40; Charles E. Frosst & Co. v. Carter Products Inc. et al, 29 Canadian Patent Reporter 145.

In all the applications hitherto made with respect to patents on drugs, the Commissioner found a "good reason to the contrary" only in Gilbert Surgical Supply Co. Ltd. v. Parke, Davis & Co., where he said:

"In connection with the intention of the applicant and the manner he intends to deal with the product, I have been left with the definite impression that he does not intend to manufacture the product at any time if he can possibly obtain it from other sources. He has admitted that the company is not making any of the products which it sells, that it has no manufacturing facilities, testing laboratories or trained staff. It has no permanent establishment at the present time. The obvious intention is to import the bulk and/or finished product for sale in Canada.

I do not think that it was ever the intent of s. 41(3) that a licence should be granted merely to import. In the first place the majority of the patents under which licences are requested are process patents and naturally you do not import a process. Subsection (3) of s. 41 goes beyond process patents and it includes product patents when the products are intended for or capable of being used for the preparation of food or medicines. The section does not differentiate between process or product patents in so far as licensing is concerned. Furthermore the manufacturing provisions of the Patent Act do not exclude patents which come under the provisions of s. 41(3). Therefore a patentee of an invention intended for or capable of being used for the preparation or production of medicine is not relieved from the obligation to work his patent commercially within three years from the grant of the patent. If my reasoning is correct, and I do not see any inconsistency in it, I must come to the conclusion that it would be unfair to grant a licence to import when the owner himself would be left open to attack for failure to manufacture. Unless very unusual and serious circumstances should prevail, I cannot agree that a licence to import is in order."⁽¹⁾

With respect to a modified application involving the same companies, he said:

(1) 30 Canadian Patent Reporter, at pp. 23-24.

". . . If a person wants to use a product by compounding it, packaging it and then sell it to others he must in the first place obtain it from a legal source of supply. Since the Commissioner has no authority to grant a licence for importation (and the applicant has agreed on this point in the Court) it follows that any legal source of supply must be licensed (by the Commissioner or the patentee) to make and sell the product. It is therefore impossible for the Commissioner to grant a licence to an applicant who does not want to manufacture."⁽¹⁾

4. Procedure with Respect to an Application
under Section 41(3)

The procedure with respect to an application under section 41(3) was described as follows by Mr. J. W. T. Michel in his evidence before the Commission:

"THE CHAIRMAN: Can you give us any idea, if there is any similarity in times, how long it takes from the making of an application for compulsory licensing to obtain it if the process goes on and is not delayed by arrangements about negotiations?

MR. MICHEL: I don't think the time can be shortened to less than seven or eight months. In the first place I have read to you Section 41 which unfortunately nobody ever thought of making regulations to govern it.

There are regulations governing Section 67 which I have mentioned before, for compulsory licensing on any industrial products and machines in which there is abuse of privilege. There are regulations for that. They do not all apply so that the first case in 1949 was started by my predecessor. He started the case. There was something that did not go in right and I called another hearing after telling them there are no rules. The Commissioner was entitled to make his own rules and I proceeded with that. There was an appeal and Justice Fournier, I believe, said 'There being no regulations for Section 41, the Commissioner has the right to direct proceedings the way he wants it'⁽²⁾, so I have been following more or less the sequence outlined in the regulations for Section 67.

(1) 33 Canadian Patent Reporter, at p. 128.

(2) Actually the case was heard not by Mr. Justice Fournier, but Mr. Justice Cameron. See Sharp & Dohme (Canada) Ltd. v. Frank W. Horner Ltd., 13 Canadian Patent Reporter 127.

I am just using what is adaptable and can be used for that purpose.

An application is made. Now, I have quite a bit of work to do. I cannot always go on it right away. Let us say I take a month or so before I order the advertisement. The application is made. Then you might think, in the first instance, this is only an ex parte affair. Well, they cannot very well be ex parte because there is the applicant and the patentee but generally the public is interested so I order the advertisement of the application in the Canada Gazette and in the Patents Office Record.

The Patents Office Record is a weekly publication of the Patents Office. It must go out on time and unfortunately it is a very complicated thing to prepare and we have to send out the material, edit the thing, four or five weeks ahead of time so when the issue is being prepared we have sent it over there. We cannot add anything more to it but sometimes I am able to push the advertisement in within three weeks if the applicant has sent me the fee. Then he gets the advertisement in the Canada Gazette. It is quicker and then I order him to serve upon the patentee the application and affidavit connected with it.

There are 60 days given to the patentee to file a counter-statement. The 60 days is taken from Section 67. After that counter-statement is filed the applicant has 30 days within which to reply.

Then I have my application. I have the counter-statement of the patentee. I have got the reply of the applicant and then from there I look at all the material and if I am satisfied, one way or the other, I am satisfied for instance I should grant the licence. If I know the applicant's firm, if I know that the firm can make that product. It has got the knowledge and it has got the money to make it, the capital and equipment, and I know from experience that such-and-such a patentee will come with such-and-such a reason to the contrary; which is always that this product is very very dangerous, should not be put into the hands of everybody else and I can supply the public demand. My price is reasonable. He will always say 'The other fellow can make it'.

In that case I grant the licence. I have granted two in the last two years, I think, without a hearing and I have been sustained^[1]. On the first one there was an appeal taken from that decision by the patentee to the Exchequer Court claiming I had overdone my powers but Justice Cameron of the Exchequer Court said that I had the power to do it.

That shortens the proceedings.

If I do not have all the facts that satisfy me, then I appoint a hearing and in order to appoint a hearing you must give them 30 clear days to come in and prepare themselves.

I hear the case and then after that in some cases I have rendered my decision without waiting for the transcript from the stenographer and in some other cases I have preferred to have the transcript so that the shortest time would be seven or eight months."

(Hearing, pp. 297-300)

"MR. MacLEOD: Nevertheless, it is probably a fact that if the patent holder wanted to resist the claim and to exhaust his legal resources, he could appeal and appeal and appeal right up to the Supreme Court of Canada?

MR. MICHEL: He could, but what I do is this. When issuing my ruling I tell them all the time: 'Now, there is going to be a license and the license is going to be effective as of today.', that is the date of my ruling. . . ."

(Hearing, p. 316)

5. The Manner of Royalty Computation
under Section 41(3)

According to the language of the section, the Commissioner, in fixing the amount of royalty, "shall have regard to the desirability of making the . . . medicine available to the public at the lowest possible price consistent with giving to the inventor due reward for the research leading to the invention." In the Parke Davis

[1] Delmar Chemicals Ltd. v. American Cyanamid Co., 32 Canadian Patent Reporter 40; Parke, Davis & Co. v. Fine Chemicals of Canada, Ltd., 32 Canadian Patent Reporter 43.

case⁽¹⁾ the Supreme Court stressed the view that the royalty set under section 41(3) must be "commensurate with the maintenance of research incentive and the importance of both process and substance". As the evidence was deemed inadequate to weigh properly all the relevant considerations, the case was referred back to the Commissioner for further consideration of the amount of royalty, the rate of which had previously been set at ten per cent of the net selling price. Subsequently, the parties settled this issue by agreeing on a rate of 12½ per cent.⁽²⁾

In his earlier decisions, the Commissioner had not investigated the research expenses actually incurred by the patentee, but had taken what has been described as a common sense approach.⁽³⁾ In the Frosst case⁽⁴⁾, he fixed the royalty at five per cent of the net selling price of the compound reduced by the proportion that the cost of the patented ingredient bears to the total cost of all active ingredients. It appears that the Parke, Davis case did not alter substantially the approach taken by the Commissioner who, in a later decision, was motivated as follows in determining the royalty rate:

"Now coming to the question of royalty, I find myself in the same usual situation where very little information has been supplied to me on which to base a reasonable reward to the inventor for the research leading to the invention.

It has been established that the invention is patented in 40 to 50 countries and that Rhône-Poulenc has granted licences at royalties ranging from 5 to 10% of the price of the finished product (tablets, I understand). On that basis it has been established that 1,000 tablets of 25 mg. dosage would bring royalty of \$8 which works out at a royalty of \$320 per kilogram of the active substance made by the patented process and that Poulenc Limitée of Montreal obtains the chlorpromazine for \$53 a kilo from a Canadian manufacturer with whom it has a manufacturing arrangement. It is very difficult for me to understand the logic of a \$320 royalty per kilogram on a product which can be made and sold no doubt at a reasonable profit, for \$53 per kilo.

(1) 30 Canadian Patent Reporter 59.

(2) Peter Kirby, op. cit., p. 43.

(3) Ibid., p. 42.

(4) 29 Canadian Patent Reporter 145.

These figures appear to have been arrived at on the basis of the suggested retail prices for prescriptions to the public and they may not represent the actual picture especially when dealing with large sales to public institutions. However I still feel that even if they were cut in half they would still be very high. Furthermore the tender price for different quantities of tablets of varied dosage would affect the royalty in every case.

On the other hand chlorpromazine like many other very potent substances must be administered in very restricted doses. The result is that a small quantity of the active substance goes a long way. One kilogram of chlorpromazine hydrochloride for instance, put up in 25 mg. tablets will produce 40,000 such tablets.

These facts must be kept in mind when one considers the due reward to the inventor for the research leading to the invention. However in fixing the reward to the inventor I am not so concerned about the considerable sums of money that go into the sponsoring, advertising and promoting of the sales of these new products.

The Act is not concerned with the finished product, it applies to that which is patented. I do not think I should distort the meaning or purpose of the Act by fixing a royalty on things which are not within the scope of the patent.

In view of the above considerations I fix the royalty at 15% of the net selling price of the active product in the crude form before tableting."⁽¹⁾

6. The Number of Licences Issued
under Section 41(3)

The compulsory licensing provisions now contained in section 41 were enacted in 1923.⁽²⁾ In his evidence, Mr. J.W.T. Michel stated that from 1923 to 1949, there had been only one application for the issuance of a compulsory licence under these provisions.

(1) Micro Chemicals Ltd. v. Société des Usines Chimiques Rhône-Poulenc, 37 Canadian Patent Reporter, at pp. 96-97.

(2) Statutes of Canada, 1923, c. 23, s. 17.

From 1949 to July 5, 1961, the date of the hearing at which he appeared, there had been 14 applications: five were granted; three were settled between the parties by the grant of licences; one was refused; the other five were still pending at the time of the hearing (Hearing, pp. 295-96).

With respect to these last five applications, the Commission was recently informed that one was granted in September 1961, ⁽¹⁾ two were withdrawn and there has been no request for action in the other two cases. ⁽²⁾ Since July 5, 1961, there have been 8 applications, all of which are pending. ⁽³⁾ If we omit the withdrawn applications and those for which there has been no request for action, there have been 10 applications since July 1960 and 18 since 1949. Of these 18 applications, 16 were made by firms that were wholly Canadian owned at the time the application was made and 2 by Canadian subsidiaries of American firms. Neither of these American firms is among the larger companies.

Reference has already been made to a return compiled by the Patent Office in answer to a question asked on February 24, 1960, in the House of Commons. This source of information indicates that with respect to patents on 3 tranquillizers and 11 antibiotics, including the most important ones, compulsory licences had been issued for the manufacture of one tranquillizer (meprobamate) and one antibiotic (chloramphenicol) and its derivatives. ⁽⁴⁾ The application granted by the Commissioner in September 1961 was for a licence to manufacture derivatives of another tranquillizer called Phenothiazine.

This record shows that very little use has been made of the compulsory licensing provisions. With respect to this aspect of the problem, Mr. J.W.T. Michel said:

"It may be that the very presence of the licensing provisions in the Patent Act has had a salutary effect on the owners of drug patents and that a certain number of licenses have been granted voluntarily, but there is still a marked tendency on the part of foreign companies holding Canadian patents to object very strenuously to the grant of licences.

. . .

. . . It seems to me if the price of drugs has been so high, why is it that no more Canadian companies have started manufacturing because, after all, the royalty is a pittance as against the profit that could be made. That is the reason why the foreign patentees don't want to grant licences voluntarily because they make much more profit by selling themselves than by just collecting a royalty."

(Hearing, pp.302, 304-05)

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- (1) Micro Chemicals Ltd. v. Société des Usines Chimiques Rhône-Poulenc, 37 Canadian Patent Reporter 93.
 - (2) Letter dated January 8, 1963, addressed to the Commission by Mr. J.W.T. Michel, Commissioner of Patents.
 - (3) Ibid.
 - (4) Green Book, pp.34-37.

"MR. MacLEOD: . . . Are there manufacturers in this country, to your knowledge, who could apply for and benefit by compulsory licenses?

MR. MICHEL: Plenty of them.

MR. MacLEOD: The facilities are there if they would take advantage of the Act?

MR. MICHEL: Plenty. There are plenty who have the knowledge and chemical skill, and who could acquire the knowhow, and there are some that are manufacturing. Some could organize and manufacture, probably because after all some of these drugs are not very difficult. Dr. Schecter was talking about cortisones today. There are some Canadian manufacturers who certainly couldn't manufacture it, but certainly not everybody, but there are some of those wonder drugs that you are talking about, there are a whole lot of them which are very easy to manufacture."

(Hearing, p. 314)

7. Voluntary Licensing

In view of the fact that it is not compulsory to register licences granted voluntarily with the Patent Office, the Commissioner of Patents, Mr. Michel, said that he did not have any information as to the number of drug patents for which licences had been granted voluntarily. He did not think that the number would be very great in view of the limited use which has been made of the provisions for compulsory licences (Hearing, pp. 303-04).

In his testimony before the Select Committee on Drugs of the Legislative Assembly of Ontario, Dr. J.K.W. Ferguson, Director of the Connaught Medical Research Laboratories, made the following statement:

" . . . In fact, we have been refused a licence for something we felt was in the national interest to be produced in Canada. I think he would be within his rights to do so, unless we compelled him to do so through the machinery of the Compulsory Licensing Act. [sic, (1) compulsory licensing provisions of the Patent Act] ."

(1) Select Committee on Drugs, hearings held at Parliament Buildings, Toronto, Ontario, Vol. 11, October 21, 1960, p. 1025.

On the other hand, Mr. K. Antoft, President of Nordic Biochemicals Ltd., said to the Commission that in the few instances in which his firm had sought licences, it encountered no difficulty in obtaining them. In this respect, his evidence is as follows:

"MR. MacLEOD: Did you have any difficulty in obtaining licenses on a patent which you wanted to take advantage of?

MR. ANTOfT: No, we never had occasion that we had to seek patent rights that were hard to get. In a few instances that we operated under license we certainly had no difficulty in procuring such licenses.

MR. MacLEOD: Do you know if licenses under those patents are normally granted generally, can almost any company get the type of license that you secured?

MR. ANTOfT: I think in one instance that the company was very concerned that we should be qualified to put out a product that was not going to give a black name to the particular preparation. In the other case, I cannot say whether other people would be granted a license readily or not.

THE CHAIRMAN: You obtained it voluntarily, not compulsorily?

MR. ANTOfT: Yes, voluntarily."

(Hearing, pp. 1430-31)

Some information of a more general character is contained in the following excerpt from the brief of the Canadian Pharmaceutical Manufacturers Association:

"There has been some regret expressed before this Commission that not enough companies are applying for compulsory licensing through the Commissioner of Patents. However, the number of applications approved at Ottawa alone cannot be used as satisfactory evidence that the compulsory licensing provision is not working in this country.

Section 41(3) is working according to the intent and expectations of its legislators. As was pointed out by the Royal Commission on Patents in its 1960 report, 'It is generally considered that the mere existence of such provisions leads to voluntary licensing which otherwise would not take place.' [Report on Patents of

Invention, Royal Commission on Patents, Copyright and Industrial Designs, 1960.] In order to bear out this point, we surveyed our member companies to determine the number of licenses which have been granted voluntarily. [C.P.M.A. Survey No. 4, 1961].

The 39 companies which replied to this survey reported they had voluntarily licensed 17 products to 32 competitors within the past six years. The breakdown is as follows:

<u>TYPE OF PRODUCT</u>	<u>DATE GRANTED</u>	<u>NO. COMPANIES VOL. LICENSED</u>
Antihistaminic	1960	1
Local Anaesthetic	1955	8
Ataractic	-	2
Antibiotic Fungicide	1960	3
Synthetic Antimicrobial	1959	1
Oral Antidiabetic	1957	1
Hormone Substance	1954	2
Antihypertensive tranquilizer	1956	1
Antiseptic	1954	1
Antibiotic	1957	2
Sali-Diuretic & Antihypertensive	1959	1
Cortico-Steroid	1954	1
Injectable	1956	1
'Various'	1957	1
Enema	1959	1
Enema	1959	1
Sulfa-Streptomycin Comb.	1956-59	4

Some of these 39 companies refused to divulge this information on the grounds that it is confidential. One major company stated, 'we do not own any patents'. Others said that they have taken voluntary licenses from competitors, but have not granted licenses themselves. One of these, a wholly-owned Canadian firm, reported receiving eight voluntary licenses from eight different companies during 1955-60, six of which are not included in the above list.

From the owner's standpoint, it is not always worth the expense involved to contest an application for a patent at Ottawa. The applicant usually applies to the owner first and where the applicant is manufacturing in Canada and has the facilities to make the product, the owner will often attempt to get the best deal possible from the applicant without resorting to legal action.

This is the rule rather than the exception. The results of a voluntary licence are not generally known at Ottawa for, as Mr. Michel has pointed out, it is not essential that a voluntary license be registered with the Patent Office."

(Association brief, pp. 74-76; Hearing, pp. 1986-92; 2189-91 and 2198)

From the excerpt and the accompanying comments (Hearing, p. 1988), it appears that, if the licensor of each of the 17 products is a different company, then 17 companies out of 39 granted 32 licences with respect to 17 products. But the number of firms which have granted one or more licences may well have been smaller than 17. This survey was concerned exclusively with Canadian companies, whether or not they were subsidiaries of foreign firms (Hearing, pp. 1987, 2198; Exhibit T-6, Survey No. 4). However, it has already been pointed out that a very small proportion of patents on drugs are issued to Canadian residents and that, with respect to antibiotics only, there are roughly 500 Canadian patents. For these reasons the results of the above survey do not indicate that voluntary licences are granted on a substantial scale.

From the Green Book⁽¹⁾, it appears that the first antibiotics to be produced, that is to say the "old" penicillins, streptomycin and dihydrostreptomycin, are not subject to tight patent control. In each case, either no patent has been issued or licences have been granted freely. But with respect to the ataraxic and the newer antibiotic drugs, the reverse is true. In most cases, there are only one or a few suppliers. When there is more than one, competition is sometimes due to the fact that the drug with respect to which a patent has been issued is also manufactured by a non-infringing process. This explains why Charles E. Frosst & Co. is selling benzathine penicillin G without any licence in competition with Ayerst, McKenna & Harrison Limited and John Wyeth & Brother (Canada) Limited, the Canadian subsidiaries of American Home Products, which holds a patent with respect to that new penicillin. Either the same explanation applies to competitors importing foreign drugs or they are liable to an infringement suit. In a few cases, competition sprang from the issuance of a compulsory licence. But very few voluntary licences have been given to competitors, if we except the cross-licensing arrangements arising out of patent interferences or designed to avoid litigation between the interested parties. This is well illustrated by the situation with respect to the five broad spectrum antibiotics: chlortetracycline, chloramphenicol, oxytetracycline, tetracycline and

(1) Green Book, para. 67, p. 33; paras. 86-103, pp. 49-55; paras. 256-375, pp. 156-201.

demethylchlortetracycline. With respect to each of these drugs, the patent is held by an American firm and the drug is sold in Canada by its Canadian subsidiary. With respect to the second, a compulsory licence has been issued; with respect to the second, third and fourth, there is competition from imports; finally with respect to the fourth, the patentee, Chas. Pfizer & Co., Inc. has licensed two firms to manufacture and sell and two others to purchase and sell. The licensing of these four firms reflects the arrangements arrived at in the United States between American firms in order to put an end to litigation. To sum up, no licence for any of these five products has been issued to a competitor on a truly voluntary basis.

8. Deterrents to Applying for a Licence

The Commission has been given a number of reasons why few licences have been issued either on a voluntary or a compulsory basis. One of these reasons is the rapid obsolescence of drugs. In this respect, Mr. R.B. Thompson, Manager of the Medical Products Department of Cyanamid of Canada Limited, gave the following evidence:

" . . . it would take him at least a year to obtain the requisite quantity and quality of product, from his plant, and by that time his product might be obsolete. . . ."

(Hearing, p. 1528)

In the following excerpt from his evidence, Mr. Thompson also pointed out, as another reason, the capital requirements:

" . . . The truth is that, if a small manufacturer wishes to produce and market under a compulsory licence, an antibiotic such as one of ours patented in Canada, and to sell that drug which is already being marketed nationally in Canada, the manufacturer would first of all have to have production facilities that would cost him probably in the region of \$1,000,000."

(Hearing, p. 1528)

"THE CHAIRMAN: This question occurs: you have a number of companies which have the equipment for producing antibiotics and if one company produces a new drug another company which had the equipment wouldn't incur this million dollar expenditure to start making this new drug if they had a licence, would they? It would just be a case -- it wouldn't be like starting from the position of having no facilities to make antibiotics?

MR. THOMPSON: The facilities are quite different.

THE CHAIRMAN: For each drug?

MR. THOMPSON: Yes, for example, the separating of crude drug out of reaction amongst fermentation vary widely according to the nature of the centrifugal equipment, extractors, filters. It is quite different. We are just in the process of purchasing for our new Welland plant, and as far as we know there is nothing quite like it, nothing suitable in Canada at the present time.

THE CHAIRMAN: What I want to get clear, does your presentation mean whatever the company, including established companies like yourselves, whenever they wish to produce a new antibiotic for which they have the formula and all the rest of it, they would have to incur the expense of something in the neighbourhood of a million dollars to start it up?

MR. THOMPSON: I would guess it. I am using the one subject I know a little about as an example. I don't mean to infer that it is always true, for example, Chloramphenicol, which is now being made in Canada synthetically, rather than by fermentation, presumably didn't require this much investment. It depends on the nature of the drug, but in many cases these new drugs are complex and becoming increasingly so, and the equipment is specialized.

THE CHAIRMAN: I want to be sure it really meant a company producing five or six different antibiotics would have to have a completely different setup costing a million dollars on the average to produce each one of these?

MR. THOMPSON: That is certainly true for a company that is making penicillin and wishes to add the tetracyclines. I don't think I know enough about these things to go beyond that kind of answer. . . ."

(Hearing, pp. 1528-30)

A third reason, given by Mr. Thompson, is the difficulty of marketing a product when another manufacturer is already established in the market:

"MR. THOMPSON: The reason why big companies who already have production facilities do not get compulsory licences to make drugs, I am talking about drugs generally now, is that their production and marketing costs would be the same as those of the patentee who has the advantage of being more strongly established in the market and in a superior competitive position.

THE CHAIRMAN: Without the basic research, I suppose?

MR. THOMPSON: Yes, but I am seeking here to express the difficulty of entering a market which is already well developed and simply competing with a company who is already there.

THE CHAIRMAN: That is the competitive problem of selling in an already established market?

MR. THOMPSON: Yes.

The larger company would far rather develop its own product than go into the market with someone else's product. Cyanamid, for example, could undoubtedly obtain a compulsory licence on a number of patent protected products. But in order to take business away from the patentee, we would have to detail the product to doctors, this is not easy when the products are identical or very similar, and we would have to pay a royalty. We are in a far better position with our own product. It is simply not profitable to market a product developed by a competitor who has fully established himself in that market."

(Hearing, pp. 1530-31)

Later the Chairman referred to Mr. Thompson's statement that the large companies found it more profitable to develop a new product in their own plant rather than to obtain a compulsory license, and asked for further elaboration of the point. He suggested to Mr. Thompson that where another company has developed a new drug and his company wishes to compete, it may be more profitable in some cases to pay a license royalty to the other company than to incur the heavy expense of a research project to develop a patentable similar drug. The answer would depend on the volume of sales, the cost of research and the amount of the royalty. Mr. Thompson commented as follows:

"MR. THOMPSON: If I were the established manufacturer in that situation, I would have no fear of that kind

of competition. Physicians once having become acquainted with a drug, and we see this in our own company, Achromycin, to which I have alluded, has been widely used by many physicians. When Declomycin, which we think is an improvement, became available we set out thinking that physicians were entitled to know about this new drug, and selfishly thought we would be less exposed to imitative type of competition. We set out to explain this in detail to physicians. We encountered the most conservative form of loyalty to Achromycin that you can imagine.

Physicians said - many, many of them have said - I am sure Dr. Warminton will bear this out - I am using Achromycin. I get fine results. My patients recover. Side-effects are no problem. Why should I change? Why should I change to Declomycin? The best efforts produce only a slow rotation.

Now consider the problem in that situation, entering the market with not an improved preparation, such as Declomycin, but an identical preparation Mr. Chairman.

THE CHAIRMAN: That is just what I am trying to get. I thought your argument is supporting the question that I am raising because if it is the identical product the physician would not be making a change.

MR. THOMPSON: On the contrary, he forms an attachment - it is difficult to remember so many new products. When he finds one that he understands and likes, he gets familiar with the packaging and he writes the prescription from memory. He becomes loyal, I suppose is the best word, to that preparation.

THE CHAIRMAN: To the name apparently?

MR. THOMPSON: Perhaps so, to the name or to the company.

THE CHAIRMAN: Or to the company.

MR. THOMPSON: To me this is the same thing. If you prefer to prescribe tetracycline Lederle rather than Achromycin, it seems to me that this is just the same thing.

THE CHAIRMAN: If the product is identical, you do not have to sell him something that is better or different, but it is identical, why should it be so difficult to get him to prescribe this one or this one or this one, all being identical?

MR. THOMPSON: They are not very often identical Mr. Chairman.

THE CHAIRMAN: I was thinking of where you are producing it under licence.

MR. THOMPSON: Each manufacturer seeks to improve by the method of formulation on his competitor. If the basic drug entering the formulation is identical, he seeks to improve the presentation of it.

THE CHAIRMAN: Does he not do that by getting another patent?

MR. THOMPSON: No. Normally one cannot do this. Ointment bases, there are many of them available, you can put your drug in petrolatum which does not readily mix with water. Another manufacturer, and this has happened, has put his antibiotic in a base which mixes readily with water and he can show how successful this was with the antibiotic. Same kind of antibiotic; produces the same treatment for the patient. Simply a case the vehicle is different.

The antibiotics are the same, the same process, comes from the same source but the finished drug differs, and he trades on that difference with the physician, and the physician is reluctant to certainly switch from day to day. He finds one and sticks to it.

The same is true of antibiotic capsules where, for example, the Achromycin capsule is a dry filled capsule in a soft, elastic capsule whereas some of the competitive preparations are in a hard shell capsule. These are differences which may affect the action of the drug on the patient. The physician generally does not take those risks. He forms an attachment to the one that is originally drawn to his attention. He is a little reluctant, a little resentful when someone comes and claims his interest for what appears to be an imitation.

THE CHAIRMAN: Even if it is an improvement?

MR. THOMPSON: If it is an improvement, you had better express yourself pretty clearly so he will understand it.

THE CHAIRMAN: I thought detail men always expressed themselves clearly to that effect.

MR. THOMPSON: We try to bring that about."

(Hearing, pp. 1555-58)

Asked whether the lack of know-how could deter some manufacturers from applying for a compulsory licence, Dr. C.H. Best, one of the Directors of the Connaught Laboratories, gave the following evidence:

"DR. BEST: . . . I know in some matters they [the manufacturers] know how to do some things that are more valuable than the patent.

. . .

MR. MacLEOD: You spoke of the know-how being sometimes more important than the other factors.

DR. BEST: Yes.

MR. MacLEOD: Would this have a bearing on compulsory licensing in this way, that an unwilling licensor if he was forced to give the license on his patent, could not [be forced to] pass along the know-how?

DR. BEST: I suppose that would be quite possible.

MR. MacLEOD: Do you think that would be an important factor in the value of the compulsory license to the licensee?

DR. BEST: I should think it might play a very important role.

MR. MacLEOD: I suppose it would depend upon the particular product and so on?

DR. BEST: Yes. I can remember one instance after the war that a group in England had know-how to sell to people on this side of the Atlantic, and they wanted several million dollars for it. The unfortunate thing about this know-how, people do not have the money for it. If they keep off and resist the temptation to acquire it, they often can learn it themselves and save the money."

(Hearing, pp. 2724-25)

According to the brief of the Canadian Pharmaceutical Manufacturers Association, the lack of economic incentives may well

be the reason why licences are not requested in greater number:

"From the applicant's standpoint, it is often the economics of the situation which determine whether a license is interesting. For example, it would not be profitable for a company to demand a license for a low-volume product on which the owner is breaking even or operating at a loss. Nor would it be practical for a company to call for a license on a biological when it does not have the facilities with which to make biologicals.

By the same token, a company is not going to demand a license for a product where it already has a competing product in the same therapeutic class. These are but a few of the reasons why licenses are not always requested, and it is incorrect to state that our licensing provision is not working because competitors are not demanding compulsory licenses from each other in profusion."

(Association brief, p. 76; Hearing, pp. 1994-95)

Finally, the Director indicated another possibility in the following excerpt from the Green Book:

"395. One explanation suggests itself. Most of the large ethical drug firms in Canada are subsidiaries or branches of foreign companies, many of which carry on world-wide operations. These firms have developed their own specialties which they promote in whatever countries they do business. It may not be considered practical for such a firm to obtain a compulsory licence which would only allow it to manufacture and sell a particular drug in Canada. If it did so, its Canadian subsidiary or branch would have to develop and market the product on its own in competition with established brands of manufacturers which would, for example, be advertised in the United States technical and scientific journals which reach Canadian doctors. It does seem to be significant that the few compulsory licences issued under section 41(3) of the Patent Act have been obtained chiefly by wholly Canadian firms."

(Green Book, pp. 224-25)

It seems likely to the Commission that any of these factors or a combination of them may be decisive in a particular situation. But to state that generally these are the predominant factors that deter a would-be competitor from requesting a licence amounts to saying that patent protection is of little value because even without it, the competitor would be prevented from entering the field

or at least would not enter it. With respect to drugs, the legislator did not want to give a monopoly to the inventor, but wanted to make sure that he would be rewarded for his research by requiring the licensee to pay him a royalty. To the extent that the patent law is not useless, but effective, either would-be competitors do obtain a licence or they are prevented by reasons other than those referred to above. These reasons may be the amount of the royalty or the delays and inconveniences involved in applying for a licence. A further possibility is that there may be a policy of the large ethical firms to respect one another's patents in order that each of them be in a position to reap to the exclusion of the others the benefits of its own patents. However no evidence of any agreement to this effect nor of the existence of such a policy has been submitted to the Commission.

CHAPTER VII

QUALITY CONTROL

1. Nature and Method of Quality Control

The Green Book, para. 223, has defined quality control as follows:

"Quality control in the pharmaceutical industry is intended to satisfy standards of potency, purity and many other factors connected with these standards. . . . the drug manufacturer is concerned with such problems as controlling the release time of the medication, i.e., whether the drug is to be released immediately or over a given length of time; the solubility of the drug, i.e., whether the drug is to be soluble in water, in the stomach or in the intestines; the vehicle or base, i.e., powder, liquid, ointment, etc., and what possible reaction there may be to the ingredients in the base; the packaging of the product; the stability over time of the drug; as well as many other factors."

(Green Book, p.142)

The nature of quality control and its methods were discussed by a number of witnesses, and more especially in the following excerpts from the briefs submitted to the Commission by:

(a) Cyanamid of Canada Limited:

". . . Perhaps we should examine briefly what we mean by the modern concept of quality control. The old concept is that when you have a laboratory technician or a chemist testing finished batches of material, you have quality control. This in fact is only a very small part of a properly organized control program, but it is the only element of quality control which is easily costed.

The modern concept of quality control of which I speak goes far beyond the mere testing of a finished product against certain standards. It is concerned with the procurement and specifications of raw materials, containers, labels and packaging supplies, the methods of production and assay, the testing procedures employed

during the various stages of manufacture, the proper sampling during manufacturing, and the methods of storage and the manner of shipment to the customers.

Our concept of proper quality control does not end with the shipment of a bottle of tablets to our customer. It is the function of quality control to continue to perform stability tests, for example, on individual field batches, comparing results against standards established on the basis of previous experience and taking appropriate corrective action when and if necessary."

(Cyanamid brief, pp.30-31; Hearing, pp.1506-07)

(b) the Canadian Pharmaceutical Manufacturers Association:

"Any experienced director of quality control knows that chemical analysis alone is not sufficient to tell whether one product is identical in every respect to another. A product can meet chemical analysis for label claim and conform with pharmacopoeia requirements, yet still contain some variation produced in the manufacture which could provide an effect on the patient not expected by the physician.

. . .

. . . Furthermore, laboratory testing of the end product is not an absolute guarantee of efficacy and safety. Such testing must be preceded by exacting quality control procedures during the entire manufacturing process."

(Association brief, pp.50, 54; Hearing, p.1912, 1917)

Some idea of the work which may be involved in the quality control of a particular drug preparation is indicated in the following extracts from an article by Mr. S. N. Conder, General Manager of the C. Ph. M. A.

"This small bottle in my hand holds 25 tablets of an estrogenic substance, which sells for around \$2.10. Like the cake your wife bakes, these tablets are made by combining a number of ingredients. But that is where the similarity ends.

In this case, the manufacturer concerned has probably conducted as many as 200 separate quality control tests. These are done to ensure that both the raw materials used and the final

product itself meet the exacting requirements for the job expected by the doctor. These tests range from ultra-violet to visible spectrophotometry, and I can assure you that the job they do is every bit as important as the imposing names they carry.

To give you an idea of the costs involved, a recording spectrophotometer for use in the ultra-violet and visible regions of the spectrum costs around \$15,000. Infra-red equipment can cost more than \$20,000 for a single instrument not much larger than a suitcase. These are but two of many such instruments required to test this medicine. It does not include the salaries paid to the scientists who operate the instruments.

In addition to these control tests, the manufacturer also runs numerous 'checks' to ensure that a particular raw material winds up in the finished product. In this case, the Montreal manufacturer concerned ran anywhere from 500 to 800 different checks on this material during the course of production and quality control procedures. Furthermore, this company also used a system of cross-checking, whereby technicians tested the work done by other checkers to eliminate the possibility of human error in this important operation.

. . . Many drugs such as the antibiotics and biologicals, are affected by deterioration; if they are not used by a certain date they lose their potency. For example, one reputable manufacturer listed 40 biological products, most of which had expiry dates ranging from six to 18 months. This same company listed 42 antibiotic preparations, each of which also carried expiry dates. It was estimated that a considerable part of the 1958 sales volume of this company was represented by preparations having a shelf life of 18 months or less.

The brand-name company which stands behind its products will take back from drug stores and hospitals, drugs which have passed their expiry period and so lost their effectiveness. This is called a returned goods policy, whereby the company allows credit for expired drugs. In some cases, the returns on biological products have amounted to as much as 40 per cent in a single year. Since these returned drugs have to be destroyed, it adds considerably to the costs of the manufacturer. . . . " (1)

(1)

S.N. Conder, "Brand Names : Why?", Canadian Pharmaceutical Journal, September, 1960, Vol.93, No.9, pp.64,123.

The problem of returns from customers of expired drugs is also discussed in the following excerpt from the brief of Cyanamid of Canada Limited:

"One of the many factors of quality control which enter into the total cost of doing business on a national scale, but which is very often overlooked by our critics is the problem of returns from customers of unsold or outdated merchandise. The severity of this factor will vary from company to company depending on what proportion of a particular company's product mix is merchandise which by government regulation must carry an expiration date. A company such as ours with a large number of antibiotic and biological products in a wide variety of dosage forms will incur heavier losses from returns of outdated merchandise than will a company concentrating on only one or two dosage forms or on products which do not carry expiration dates.

In Canada all antibiotics, regardless of dosage form, must carry an expiration date. The dating varies with the dosage form and the antibiotic itself. For example, Declomycin Capsules carry a three year expiration date, whereas Declomycin Pediatric Drops carry a one year expiration date.

It is an element of our published policy to accept for full credit as a return from our customers any product in an unopened package which becomes outdated in the customer's stock. In 1960, for example, such returns amounted to more than 3% of our total sales. On individual products carrying relatively short expiration dates, such as one year from date of manufacture, it is not unusual to experience returns of over 10%.

Since we were the first company to make available supplies of Asian 'Flu Vaccine in Canada in the fall of 1957 to combat the spread of Asian 'Flu, our 1957 sales of this vaccine were naturally quite large. However, this product carried an expiration date of 18 months when properly stored under refrigeration. As the material remaining in our customers' stocks became outdated in early 1959, our returns mounted. Over 10% of the vaccine sold during this Asian 'Flu epidemic in the fall of 1957 has been returned to us for full credit, and because of the nature of this product, these returns have no salvage value to us, and are destroyed as they are received from our customers.

In fact, over 90% of all returns are destroyed as non-salvageable, the only items that can be salvaged being items in good date, packed in pilfer-proof sealed packages, and not requiring refrigerated storage. Unless we are absolutely certain that a package could not have been opened after it left our possession originally, we do not attempt to offer this package for sale a second time. This again is an example of our concept of our total quality control."

(Cyanamid brief, pp.32-33; Hearing, pp.1507-09)

2. Standards of Quality Control Maintained by the Industry

The role of the Federal Government in the inspection of drugs with respect to quality control will be dealt with in Chapter VIII of this report. It was submitted to the Commission that the regulations administered by the Food and Drug Directorate do not guarantee a desirable standard of quality control, and that the standards maintained by the industry are higher than those required by such regulations. These views were expressed in the following excerpts from the briefs presented by:

(a) the Canadian Pharmaceutical Manufacturers Association:

"... most ethical pharmaceutical manufacturers now maintain strict control in their manufacturing operations to ensure the efficacy and safety of products and their consistency from batch to batch. This is a form of self-regulation, as there is presently no law requiring such control for pharmaceutical preparations. There can be no doubt that this is in the best public interest, and we believe that every product imported or made in Canada should be produced in conformity with sound manufacturing principles and under proper quality control procedures. Obviously, it would be most difficult for any government body to guarantee every batch of products sold."

(Association brief, p.54; Hearing, pp.1917-18)

(b) The Canadian Pharmaceutical Association, Inc. :

"It is repeated that the Canadian Pharmaceutical Association must take the stand that the degree of quality control of drug products that is mandatory under present Regulations of the Food and Drugs Act is not such as to give sufficient assurance to the pharmacist that any given batch of the products of all manufacturers will meet the required specifications."

(Association brief, p.41; Hearing, pp.2398-99)

Dr. C. A. Morrell, Director, Food and Drug Directorate, Department of National Health and Welfare, stressed the importance of the manufacturer's quality control procedures:

". . . In fact, he [the drug manufacturer] is the first one and the most important one in this chain of quality control. He has the opportunity to check the raw materials, to supervise the compounding of these things and be able to check the product when it is finished. He has the opportunity to check every batch or lot that he makes. A control agency such as ours can only, and perhaps should only spot check, so that the manufacturer has the first and main responsibility for the quality control of his product.

MR. HANSARD: That is it is his responsibility to do all these things that are necessary?

DR. MORRELL: Yes.

MR. HANSARD: And the more particular drugs and types of medicines he is handling the more of this work he has.

DR. MORRELL: Yes."

(Hearing, p.145)

Further excerpts from the brief of the C. Ph. M. A. indicate the limitations of an official pharmacopoeia and, as well, the possible variations in a drug product made by various manufacturers even when the products of all those manufacturers meet the minimum requirements of an official pharmacopoeia:

"In the case of the United States Pharmacopoeia, for example, the requirements are essentially minimums, and the standards set by most pharmaceutical manufacturers are generally higher in terms of efficiency.

Here are a few instances of this:

1. Regarding Tetracycline Capsules: Studies of the absorption of tetracycline into the blood stream after administration of the capsules, showed that different formulations produced different concentrations of tetracycline in the blood. It has been found that if calcium compounds, like calcium diphosphate, are added as a filler during encapsulation of the tetracycline, it will bind some of the tetracycline and prevent it from being absorbed. This would result in much lower tetracycline blood concentrations.

It has also been found that citric acid will markedly improve the absorption of tetracycline and give much greater concentrations of this drug in the blood. Also, glucosamine may enhance the absorption of tetracycline. The USP does not specify that calcium should not be added to a capsule formula, nor does it specify that substances like citric acid and glucosamine would aid in the absorption of tetracycline. Accordingly, there could be differences in a product quite important to the patient, and yet they would be USP tetracycline capsules.

2. In the preparation of procaine penicillin G suspension, and sterile penicillin dihydrostreptomycin for suspension, each manufacturer has to make his own formulation to meet his definition of a satisfactory product. The USP permits the use of one or more suitable, harmless suspending or dispersing agents and preservatives, but does not state what these should be.

There are a number of such substances, such as carboxymethyl cellulose, polyvinylpyrrolidone, the tweens, lecithen, etc. Depending upon the manufacturer's particular formula, some of these preparations remain suspended for longer periods of time than others. Some may be thicker or thinner suspensions. Others may produce considerable foam when shaken. Still other companies treat the surface of the glass with silicone to prevent the preparations from adhering to the glass surface.

All of these may pass USP requirements, but a physician may prefer one company's product over that of another, because of its ease of suspension, viscosity and other similar factors.

3. Regarding ointments, the USP states: 'In official ointments and suppositories the proportions of the substances constituting the base may be varied to maintain a suitable consistency under different climatic conditions provided the proportion of active ingredients is not varied'.

It is recognized that variations in the proportions of the ointment base could cause differences in the absorption of active drugs through the skin. Also, some manufacturers in preparing ointments micropulverize the active drug ingredients so that they are extremely smooth and non-gritty. This could be particularly important in the case of ophthalmic ointments where lack of irritation due to the medicament itself may be a factor in why the doctor would prefer one product over another.

4. Sterile procaine penicillin G with aluminum stearate suspension is made by suspending procaine penicillin G in oil that has been gelled with two per cent aluminum monostearate. There is a definite art in preparing this aluminum monostearate oil gel. If the gel is not prepared properly, upon injection the concentrations of penicillin remaining in the blood may be of a considerably shorter duration than with a properly prepared gel.

Consequently, it was found that one company's product gave penicillin blood concentrations, after the injection of 1.0 ml. containing 300,000 units, for 96 hours. Other preparations tested varied in their prolongation of penicillin blood concentrations from 24 to 72 hours. As the USP does not specify the manner in which the gel should be prepared, there can be important differences between two products although both would pass USP requirements."

(Association brief, pp.51-53; Hearing, pp.1912-15)

With respect to the varying standards of quality control maintained by the manufacturers, Dr. J. D. Ross, Minister of Health in the government of Alberta, testified as follows:

"THE CHAIRMAN: Do you know, Doctor, whether in the profession in Alberta, there is a strong feeling that drugs are not equal even though they may be chemically the same, that some drugs are inferior, haven't been made with so much quality control, purity control as others, and when they are prescribed they are anxious that the exact prescription be provided [and not another drug which may be chemically identical] but which in their opinion may not be so useful?

DR. ROSS: That is an opinion held by some doctors. Some in our own hospitals feel that way about certain types of drugs, and that is why we feel it is necessary that there should be rigid control of the compounding of these drugs by the manufacturing companies"

(Hearing, p.869)

3. The Position of the Retail or Hospital Pharmacist
with Regard to Quality Control

Several witnesses testified to the fact that the retail druggist or the hospital pharmacist could do very little by way of guaranteeing to the recipients of drugs the quality of the products supplied by the manufacturers and, in the case of drugs dispensed in the form supplied, the pharmacist depends on his knowledge of the reputation of the manufacturer. This appears clearly from the following excerpts:

(a) From the brief presented on behalf of the Canadian Hospital Association by its Assistant Director, Mr. George McCracken:

"ANALYSIS - This concerns the degree to which drugs are analyzed or tested upon receipt at the hospital or at least at some time following receipt. Analysis can mean a number of things, but we can say that in very few, if any, instances is there a chemical analysis done by pharmacists in hospitals insofar as the general drug supply is concerned.

Two main reasons may be cited for this: firstly, even where a pharmacist is on staff, our experience is that he is extremely busy doing his regular duties and there literally is no time to do this type of work. Also, the facilities required would be extensive and these ordinarily are not available in hospitals. The pharmacist strives to purchase on the basis of known quality and relies to a major degree upon the reputation of the supplier and his own experience with that firm or firms. In short, since he has not the time nor facilities to do a chemical analysis, he tends to buy products which he has come to depend upon for maintenance of quality standards.

One might well ask, upon what does the pharmacist base his dependence upon these items? This is a combination of several things. There is a physical or sense analysis in that he is able to do a visual inspection, detecting variations in size, texture, etc. as well as detecting, in some instances, odours which do not conform with what he has come to expect. In short, this experienced person

as in other lines of endeavour, develops certain rule-of-thumb criteria which stand him in good stead. The opinions of the medical staff as to patient reaction to drugs prescribed are, of course, very important and these, too, provide their measure of evaluation as to the effectiveness of drugs and supplies."

(Association brief, pp.14-15; Hearing pp.1757-58)

(b) From the brief presented on behalf of The C. Ph. A. by its Secretary-Manager, Mr. J. C. Turnbull:

"Quality and Quality Control:

The use of batch numbers, datings, storage instructions, etc., on manufacturers' labels permits a high degree of control over their products. To such information the pharmacist adds his own knowledge of minimum requirements and standards, physical qualities and chemical potentials to assist him with his handling of a particular drug preparation. However, he and the physicians of his community seldom have any way of knowing, or of establishing the full extent of the quality of the product other than through the established reputation of the manufacturer.

Quantitative analysis -- usually beyond the scope of the individual pharmacist in private or institutional practice, due to its expense and the time and equipment necessary -- of the finished product does not, by itself, necessarily establish all pertinent aspects of quality. An assurance of quality control in all steps of production, from the raw product to the finished dosage form, should be the right of every patient. . . "

(Association brief, pp.33-34; Hearing, pp.2359-60)

4. The Importance of Quality Control

In certain diseases high standards of quality control may be of vital importance to the patient in assuring accuracy in the dose of the drug being administered to him. In this connection, the following evidence was given to the Commission:

(a) By Dr. J. P. Gemmell, Associate Professor of Medicine at the University of Manitoba:

"Doctors always say beware the man who talks of one case, but this will illustrate the difficulty that you get in. I have a

patient who is entirely dependent on the fact that she receives cortisone, and this is relatively important, the amount of the cortisone. My prescription read cortisone, which is a generic name, 25 milligrammes, half a tablet four times a day. Her husband called me and said she was not well at all, so I put her in hospital and she was running a high fever and feeling terrible. I asked if she was taking her medicine and she said that she was. Obviously she needed more cortisone, so I gave her intravenous cortisone and the minute I did she became a brand new woman.

The next morning I asked her where did you get your cortisone, and she said from the druggist. I said have you got it with you and she handed me the thing, and it looked like no cortisone medication I had ever seen in my life. So I 'phoned the pharmacist and said: 'What kind of cortisone is this patient getting?' He said: 'In the past I have given her such-and-such a company which is very reputable, and so-and-so, which is also reputable, but lately as this is very expensive I have given her a much cheaper form of drug'.

It is my opinion, I have no proof, it is my opinion, the proof satisfies me, that this didn't contain anything like the amount of cortisone that it was supposed to, . . . "

(Hearing, pp.527-28)

"THE CHAIRMAN: But, generally speaking, would this be your position: If you were giving a prescription to a patient, for reasons of quality control you would tend to specify a trade name product of a manufacturer whom you considered to be reliable?

DR. GEMMELL: I would say this is only applicable in certain very critical drugs, and I think cortisone, persons whose life depends on an accurate dose level of this product. Otherwise, if you came to me for maybe, a sleeping pill or antacid or aspirin, I am sure this is not at all critical. "

(Hearing, p.530)

(b) By Dr. Mark Nickerson, Professor and Head of the Department of Pharmacology and Therapeutics at the University of Manitoba:

"THE CHAIRMAN: Because there is, as we have seen this morning a great deal of hesitation at least on the part of the medical profession to prescribe drugs about which they may have some mental reservation as to the sources and therefore the quality. Do you feel a good deal of that difficulty could be overcome?

DR. NICKERSON: I would expect it could. I can recognize this mental reservation and it is frequently called to my attention. I am frequently asked about this. I am unable to give a specific answer as to just what extent the particular drug can be relied on.

I think at the present time it is very difficult to give that sort of opinion.

I am sure there is more build-up of scepticism, shall we say, about the quality of drugs than is actually justified today because the tendency is when you give a drug to a patient and you do not get the response you expect from the patient very often you attribute it to the fact this drug was from some supplier you did not know.

There are a few cases, I think, comparable to the one Dr. Gemmell mentioned in which with the patient in hospital with the administration of another preparation and so on you have actual evidence of the change in the patient and consequently good inferential evidence at least that the drug is at fault. These things are very rarely controlled."

(Hearing, pp.562-63)

5. Quality Control Considered in Relation to
Generic-named Products and Brand-named
Products

An important question which arose during the course of the hearings before the Commission was whether the quality control exercised in the manufacture of drugs sold by brand names is superior to that exercised in the manufacture of drugs sold by generic names only.

On this matter, Dr. C. A. Morrell, Director, Food and Drug Directorate, Department of National Health and Welfare, testified as follows:

"MR. MACLEOD: Can you express any opinion on the perennial argument of the value of brand names as against the generic name drugs? Is there any particular magic in brand names?

DR. MORRELL: No. I was saying to somebody just outside, anybody can register a brand name. It wouldn't matter at all who he is, whether he knows anything or not. All he has to do is get the registration for it, is that not true?

MR. MACLEOD: So, Doctor, you would assume there might be good drugs sold under brand names and poor drugs?

DR. MORRELL: I am sure there are.

MR. MACLEOD: And the same may equally be true of generic drugs?

DR. MORRELL: I am sure there are.

MR. MACLEOD: It is not a significant division.

DR. MORRELL: No. In my opinion the significant thing is the facilities, ability and attitude of the manufacturer that is important, not the brand name."

(Hearing, pp.134-35)

Dr. C. S. Marshall, Administrator for National Health Services, Department of Public Health, Province of Nova Scotia, testified as follows:

"MR. MACLEOD: Do you have any experience, Doctor, in purchasing tranquilizing drugs under generic names and under brand names?

DR. MARSHALL: Yes, we had quite an experience with that. We originally purchased under brand names and then we changed from brand names to the more common and larger used drugs. Chlorpromazine, we changed from the brand name to the generic with considerable saving of money.

MR. MACLEOD: What about the quality of the drug?

DR. MARSHALL: When we did this there was a very great concern -- there was a lot of ideas suggesting the notion that the brand name drugs weren't to be relied. . .

THE CHAIRMAN: The brand name?

DR. MARSHALL: Yes -- the un-brand name, the generic weren't to be relied on. There were several suggestions that indicated that we would be doing our patients a dis-service if we stopped buying brand names. We weren't too certain about this. We were a bit concerned.

. . .

. . . When we started there were really three suggestions as to whether the ordinary generic name was not satisfactory: (1) that the amounts were not right, (2) that they were not mixed as well and that the amount of the drug would vary from tablet to tablet. This was the proposal as to why we should stick to brand names in order to be sure you were getting exactly the right dosage.

THE CHAIRMAN: Is this a criticism that they said might be there, or was it what you found as a fact to be true?

DR. MARSHALL: No, this was suggested to us when we were considering the change, that if you were buying, the brand names were so well established, or they were more careful in their preparations and mixed them better, their dosage was more reliable; and this was a proposal, a suggestion, a reason as to why we should stick to brand names rather than move to the generic names.

THE CHAIRMAN: Where would that suggestion come from?

DR. MARSHALL: Apparently they came from the people who were representing the brand names.

THE CHAIRMAN: Coming from the manufacturers of these brands themselves?

DR. MARSHALL: Yes.

. . .

The third thing I wanted to say was that the drugs were said not to be packaged as well and that they were more fragile and would break. There was some truth in this last point, although that has been corrected and the generic drugs now are packaged as well.

Anyway, we tried out small amounts and as near as we could find out the patients' end results were as good on the generic as on the brand names and they were so much cheaper.

THE CHAIRMAN: This is chlorpromazine you are speaking about?

DR. MARSHALL: Yes, chlorpromazine and as far as our trials were concerned we could distinguish no difference in the patients.

There was at the beginning a little greater tendency, definitely a greater tendency for the drugs to be more fragile, to break up slightly, so that when you order say 1,000 you would find more breakage in this group than in the trade name product, but the amount was not very great and you still saved a great deal of money and in the later products we find they are no more fragile than any of the others.

So that we have stuck pretty consistently after some misgivings and wondering ourselves whether there were differences, trying it out very carefully, to see whether you could distinguish any difference, and we found that we could not and so we finally in the case of chlorpromazine went directly to this, and I may say that there is a considerable saving."

(Hearing, pp.450-54)

With respect to this matter, the brief of the Canadian Hospital Association contained the following views:

". . . The term 'generic' should in no way connote a cheaper product in the sense of an inferior one and it is here the matter of quality arises. A drug may be ordered by its generic name from what is known as a generic house, and, as in the case of all purchases, the hospital must be in a position to feel it can rely upon the product or supplier. In point of fact, a number of hospitals do have stocks in varying proportions as to drugs purchased under their generic name and under designated brand names. The

preference and wishes of the medical staff for particular items are important factors in the establishment of the stocks and to the extent that these are professional people with specialized knowledge of the effect of certain preparations in their treatment regimes, must be accorded full weight in any purchasing policy."

(Association brief, p.11; Hearing, p.1754)

6. Quality Control in Relation to Domestically
Produced and Imported Drugs

The brief presented on behalf of The Pharmaceutical Association of the Province of British Columbia by its Registrar, Mr. Douglas Denholm, contains the following statement with respect to Canadian-made and imported drugs:

" . . . We hold no views as to whether small manufacturers are preferable to large or as to whether drugs manufactured in Canada are preferable to those imported from abroad. Our interest rather has centred on what control procedures have been followed by the manufacturer during the course of production."

(Association brief, p.16; Hearing, p.1322)

With respect to this matter, the following evidence was given by:

(1) Mr. J. R. W. Shaw, Departmental Purchasing Agent, Department of Veterans Affairs:

"MR. MACLEOD: Does the policy of purchasing under generic names raise any questions or difficulties in relation to quality?"

MR. SHAW: It has raised difficulties in relation to quality.

MR. MACLEOD: Perhaps you would just explain.

MR. SHAW: If I may say, the use of generic names has in the past two or three years brought into the drug purveying picture people, firms, I should say, who offer the drug by its generic name from little known foreign sources of

supply, and as the policy of the Department is to provide the proper drug of acceptable quality to the treatment services, one of the provisions of our form of tender is to state the country of origin of the drug supplied, and if the tender indicates that the drug is of foreign origin we must, of course, ensure that it meets the laid down standards for that drug, either U.S.P. or any of the other authorities on drugs. In order to determine that it meets this quality, the drugs are referred to the Pure Food and Drugs Laboratory, Department of National Health and Welfare.

. . .

THE CHAIRMAN: You mentioned drugs of foreign origin. That has a different significance in some people's minds to others. What do you mean 'foreign origin'?

MR. SHAW: Other than the United States and Canada.

THE CHAIRMAN: The United States is not foreign in that sense?

MR. SHAW: No. I am talking of those which originate in Denmark, Italy, France.

THE CHAIRMAN: Perhaps Britain?

MR. SHAW: Yes.

THE CHAIRMAN: Everywhere except the United States and Canada?

MR. SHAW: Yes.

MR. MACLEOD: Is it a matter of routine that you test every drug that comes from a foreign source?

MR. SHAW: If a drug is supplied by other than what we have grown to know to be established sources of supply, yes, it is routine.

MR. MACLEOD: In respect of drugs that you buy manufactured by Canadian companies, made in Canada, are there some companies that in your experience put out drugs that may be of doubtful quality?

MR. SHAW: If one regards the necessity of testing or the routine of testing as doubting the quality, I would say the answer is yes. But I don't say that we doubt the quality.

MR. MACLEOD: That is the point I was coming around to. When you make purchases from certain Canadian companies do you feel that they should be tested?

MR. SHAW: Yes, there are certain Canadian companies which we do feel that they should be tested.

MR. MACLEOD: Are there companies or products you accept as a matter of course?

MR. SHAW: We do accept the products of some Canadian companies without testing, but I would say it is prior to purchase. The products supplied to hospitals, if the name of the supplier has changed then I would say the Chief of Medicine would have the laboratory run a test to make sure it would do the job it is required to do.

MR. MACLEOD: Can you give any estimate or any description of the quantity or amount of drugs that have had to be turned back that didn't meet your standards? Is it the exceptional thing or ---

MR. SHAW: Oh, it is the exception. Out of possibly fifty tests I would say that not any more than three or four products have been rejected.

THE CHAIRMAN: That is from all sources, Mr. Shaw?

MR. SHAW: Yes.

MR. MACLEOD: Are you sufficiently knowledgeable of the pharmacy of drugs to express any opinion whether they were serious differentials?

MR. SHAW: I receive the reports from the Pure Food and Drug Laboratory, and in the main the rejections have been on the basis of not meeting the potency required. Whatever the test requirements are, U.S.P. or whatever other authority there are certain maximum and minimum limits, and if the drug does not fall within those limits we are advised it is either below or otherwise. I have had rejections on the basis of improper labelling, not in conformity with the labels laid down by the Pure Food and Drug Act. "

(2) Mr. J. C. Turnbull, General Manager and Secretary-Treasurer of the C. Ph. A. :

"MR. TURNBULL: . . . Possibly I may, in a generalization, sir, indicate our first doubts about the products being imported from foreign countries of unknown control procedures, and this type of thing. That caused considerable consternation on the part of the pharmacy practitioner, in that suddenly he was confronted with a situation that was new to him, and up to that particular time he had no assurances based on experience of the controls and what-not in those countries. Gradually this information becomes known.

Also when a new distributor suddenly appears before the pharmacists, and there is no basis of experience that this new distributor is either manufacturing himself or obtaining products from sources which are, as I said, unimpeachable in the field.

THE CHAIRMAN: You mean this in the sense really that it is rather an agnostic position. You do not know that satisfactory quality control measures are being taken rather than that you do know they are not being taken?

MR. TURNBULL: That is correct.

THE CHAIRMAN: Sometimes, and this is understandable, the pharmacist might decline to use a product of a certain company simply because he has not had any information satisfactory to him?

MR. TURNBULL: That is correct.

THE CHAIRMAN: That their products are prepared under conditions that are proper and suitable but he is passing no judgment on their actual suitability or reliability. He is merely saying 'I don't know, therefore I don't use them'?

MR. TURNBULL: Yes."

(Hearing, pp.2399-2400)

"MR. MACLEOD: My point is a very narrow one, it is simply whether you would - let us take a Lilly product, a Lilly product manufactured in the United States as being as good as one manufactured in Canada?

MR. TURNBULL: Whether I would?

MR. MACLEOD: Yes.

MR. TURNBULL: Yes.

MR. MACLEOD: Would the same hold true - I have given one American company - in England, the Burroughs Wellcome; Glaxo-Allenburys, the British Drug Houses, any of the established firms, would you regard products sold by those companies in Canada but manufactured in England as being the equivalent of products manufactured in Canada?

MR. TURNBULL: You are seeking a generalized opinion without reference to any specific product. I, of course, must have my opinion recorded in general terminology all based around the one word 'yes'.

MR. MACLEOD: Would you assume that the same degree of quality control had been exercised in the case of all products manufactured by such a company in the United States or in England as would be carried out if the product had been manufactured by the same company in Canada?

MR. TURNBULL: You mentioned the Eli-Lilly Company in the United States and you mentioned the Burroughs Wellcome Company in the United Kingdom - my answer would be yes, sir.

THE CHAIRMAN: Are these opinions that you are giving us now, are these intended to be your own personal opinions or would they be the opinions which your Association would support?

MR. TURNBULL: Regrettably, Mr. Chairman, I don't recall the Association as such writing any opinions of this nature. I don't know that the occasion has ever arisen that it has had to discuss these specific instances and relate its opinion from one company to the other.

THE CHAIRMAN: It is simply your own personal opinion?

MR. TURNBULL: Yes, in my position as Secretary-Manager of the Association and as a personal opinion, yes."

(Hearing, pp.2689-90)

(3) Mr. J. R. Gilbert, President of Gilbert & Company, Toronto:

"MR. MACLEOD: Based on your experience, can you give the Commission any information on the quality of the basic drug you obtain from Italy or from Denmark?

MR. GILBERT: We have the occasional difficulty. I haven't been very happy with the finished products. That was one of the motivations for doing my own manufacturing, but we would have no complaint with the material because we only buy on specification.

MR. MACLEOD: Does it, in fact, meet your specifications?

MR. GILBERT: If it isn't [sic] we don't use it. There have been the odd instances.

MR. MACLEOD: Do you find it possible by using specification to get basic drugs of high quality from Italy?

MR. GILBERT: Yes.

. . .

MR. MACLEOD: You said a moment ago that you found you were somewhat dissatisfied with some prepared dosage forms you purchased. What has been your experience there? Would you elaborate on that?

MR. GILBERT: The products assayed all right. I wouldn't consider them pharmaceutically elegant.

MR. MACLEOD: Did you say for that reason you had discontinued importing some of these forms?

MR. GILBERT: Correct.

THE CHAIRMAN: I am intrigued with the phrase 'pharmaceutically elegant'. Is that a pharmaceutical term?

MR. GILBERT: I think a pharmacist would understand what I am talking about.

THE CHAIRMAN: We may not.

MR. GILBERT: You want a product you can handle and look at with pride, clear-cut tablets, proper shapes, unmottled, packaged properly.

THE CHAIRMAN: It relates to the appearance of it?

MR. GILBERT: That is correct. It has nothing to do with the quality, the intrinsic quality of the drug.

THE CHAIRMAN: Nothing to do with the intrinsic quality or safety?

MR. GILBERT: That is correct."

(Hearing, pp.2842-45)

7. Quality Control in Relation to Large and Small
Drug Manufacturing Firms

With respect to the relative merits of large and small manufacturers in relation to quality control, the Green Book made the following reference to and comment on a letter dated January 15, 1960 written by Mr. Douglas Denholm, Registrar, The Pharmaceutical Association of the Province of British Columbia:

"27. The fact that every batch of drugs sold in Canada is not inspected has some bearing upon the readier acceptance that is generally accorded drugs put out by large, as compared with small, manufacturers. For example, a letter from the files of the Pharmaceutical Association of the Province of British Columbia, written by the Registrar, clearly implies a distrust of the low-cost drugs and pharmaceuticals of 'fringe manufacturers' whose products are not subject to continuous quality control measures and the quality of which cannot, therefore, in the opinion of the Registrar, 'be guaranteed' (Serial 298)
. . . "

(Green Book, p.12)

The letter referred to above was sent by Mr. Denholm to a member of the Association who was pharmacist at the R.C.A.F. Station at Comox, B. C., and read in part as follows:

"Thank you for your letter of January 13th relative to the purchase of inferior drugs and pharmaceuticals by departments of the federal government.

This whole problem revolves around the looseness of provisions of the Food and Drugs Act which does not enforce quality control procedures at the manufacturing level thereby making it possible for fringe manufacturers (or as you so aptly call them, basement manufacturers) to place on the market low-cost drugs and pharmaceuticals whose quality cannot be guaranteed. We have been doing a good deal of public relations work on this point but time and again have had it thrown back to us that if drugs were of inferior quality, how is it that the Departments of Veterans Affairs and National Defence use them? We have been replying in general terms that price rather than quality appears to be the first criterion in drug purchases by departments of the federal government. Your letter is the first concrete piece of evidence we have received to substantiate this statement and I would dearly love to make wide use of it in our present campaign."

(Serial 298; Hearing, pp.1309-10)

The letter to which Mr. Denholm was replying had referred to "cheap copies of drugs being purchased by Ottawa for use by members of the Armed Forces and their dependents." (Serial 299-300; Hearing, p.1305).

Mr. Denholm said in evidence that he did not know specifically which drug companies did not have continuous quality control nor did he know whether they manufactured the drugs in question in Canada or elsewhere. He said that the opinion set out in his letter was based on the information which he had received from the pharmacist serving in the Armed Forces who, he felt, was expressing his professional concern as he would have no economic interest in the matter (Hearing, p.1311 and pp.1323-28).

In a letter to the Commission dated November 26, 1962 Surgeon Rear Admiral T. B. McLean, Surgeon General, Canadian Forces, made the following statement with respect to the quality of the pharmaceuticals dispensed to the members of the Canadian Armed Forces:

- " (i) The Pharmaceuticals available from CFMS Medical Supply Depots for treatment of personnel of the Armed Forces are as listed in the Catalogue of Medical Supplies and Equipment, Canadian Forces,
- (ii) Each Pharmaceutical is catalogued under its 'common name'. The 'common name' is, as defined in the Canadian Food and Drug Act and Regulations, 'the name in English or French by which the drug is commonly known'. This method of nomenclature is also popularly known as the 'Generic' name,
- (iii) Each Pharmaceutical in the Catalogue has its own specification described as 'Department of National Defence Medical Purchase Description (MPD)'. The MPD is the minimum standard for any item of medical material in use in the CFMS and forms part of the contract governing the quality of the material being purchased. The reference texts used to prepare these specifications include the British Pharmacopeia, United States Pharmacopeia and the Canadian Food and Drug Regulations. The MPD includes the necessary details to define the description, identification, standards, assays, labelling, packaging etc. These MPDs are under constant review in order to maintain the best possible standards by taking advantage of scientific and technological advances.
- (iv) Contracts for the supply of Pharmaceuticals are processed in the same manner as contracts for any other supplies required by Department of National Defence. The requirement for a Pharmaceutical is initiated by my staff in the form of a Contract Demand. This Contract Demand is passed to the Deputy Minister's Office (A/DM(R)) for approval, then forwarded to the Department of Defence Production (DDP). DDP issues a contract by their tender system for the requirement as laid down by the Department of National Defence MPD governing the item. Pharmaceuticals are accepted off a contract only after each lot or batch has been tested by DND Inspection Services, and found to comply with all of the requirements delineated in the MPD.

- (v) My office had no knowledge of any report in relation to the supply of substandard drugs to RCAF Station Comox. Only one complaint had been received from RCAF Station Comox in 1960 which had to do with the palatability of an antacid tablet. This complaint was not considered valid and they were so advised.
- (vi) The allegation that substandard drugs have been supplied is definitely denied. By reason of standards required by the MPDs and inspection of the Pharmaceuticals prior to delivery off a contract, it must be apparent that the quality of the Pharmaceuticals supplied by the CFMS to the Canadian Forces is of the highest order."

The relative merits of large and small manufacturers in relation to quality control are discussed in other evidence received from the following sources:

(1) Mr. J. W. R. Shaw, Departmental Purchasing Agent, Department of Veterans Affairs:

"THE CHAIRMAN: There is just one point I would like to get on the record. You refer to purchasing from some drug companies without pre-purchase testing. Now, there is some information in the green book prepared by the Director of Investigation and Research that indicates, in some quarters at any rate, there is the feeling that the larger drug companies are more reliable as to quality than the smaller ones are. I was wondering if your experience, that is in purchasing without having drugs tested previously, applies only to the larger well established drug companies or are there a number of smaller drug companies you find sufficiently reliable?

MR. SHAW: There are some - there are smaller drug companies that are considered as reliable as the larger ones.

THE CHAIRMAN: Some are quite as good for the product they make?

MR. SHAW: Yes.

THE CHAIRMAN: As the larger ones?

MR. SHAW: That is quite true, sir."

(2) Dr. Mark Nickerson, Professor and Head of the Department of Pharmacology and Therapeutics, Faculty of Medicine, University of Manitoba:

"I might say that the difference between, shall we say the large manufacturers and some of the smaller producers, is not as great as we sometimes think. The Medical Letter has done two studies, one on penicillin and one on prednisone, in which they went out and bought as many different brand names as they could at a retail pharmacy, and then had these analyzed by a laboratory. In the case of prednisone they obtained samples ranging from \$1.00 to nearly \$18.00 a hundred tablets. They found only three of these which didn't meet the official U.S.P. specifications, and the difference in these three was such that it would not make any difference to the patient. So that indicated that there are substandard batches on the market from time to time, there are probably even today.

THE CHAIRMAN: Was this sampling of trade names only?

DR. NICKERSON: No, all the different suppliers they could get their hands on.

THE CHAIRMAN: Including some by generic name?

DR. NICKERSON: Yes."

(Hearing, p.548)

(3) J. L. Summers, Associate Professor of Pharmacy, University of Saskatchewan, Director of Pharmaceutical Services of the University Hospital, Saskatoon:

"MR. MACLEOD: Does your hospital in fact use the products of some small firms and small manufacturers?

PROF. SUMMERS: This is a difficult question to answer because I don't know who you mean by 'small manufacturers'.

MR. MACLEOD: Does your company use the products of Nordic?

PROF. SUMMERS: Yes.

MR. MACLEOD: I mean your hospital.

PROF. SUMMERS: Yes, indeed.

MR. MACLEOD: And finds them quite reliable?

PROF. SUMMERS: Yes.

MR. MACLEOD: In considering that as a small firm, are there others in the same category?

PROF. SUMMERS: Yes. These are largely specialty firms; firms who specialize in a very narrow range of products requiring people of a high degree of specific technical and professional skills such as Nordic in their extraction of glandular products.

MR. MACLEOD: Within that field their products are quite as good as anybody else's?

MR. COOK: I wonder if the witness should be required to evaluate.

PROF. SUMMERS: Can I say this ---

THE CHAIRMAN: Perhaps the question should be not as good, but is it satisfactory to you.

PROF. SUMMERS: The answer is yes, we use Nordic products and they appear to be satisfactory.

MR. MACLEOD: Let me put it to you this way: In your opinion does the size of the supplying firm have any particular significance in relation to the quality of its products?

PROF. SUMMERS: No, sir. I believe that the thing that does relate, as Dr. Morrell stated, this is our guide line, sir.

MR. MACLEOD: In your experience is Dr. Morrell's statement more applicable to large firms than to small ones?

PROF. SUMMERS: Not necessarily so."

(Hearing, pp.2270-72)

(4) Mr. J. C. Turnbull, Secretary-Manager, C. Ph. A., reading from his Association's brief:

" . . . An assurance of quality control in all steps of production, from the raw product to the finished dosage form, should be the right of every patient, whether ambulatory or hospitalized, who, quite correctly, expects to receive nothing but the best to alleviate his illness. Here again, practitioners who render health services, turn to the products of manufacturers known to them to be inherently reliable, regardless of their 'bigness' in the industry. Quality infers pharmaceutical excellence; control is the means by which excellence is achieved."

(Association brief, p.34; Hearing, p.2360)

The following testimony of Dr. C. C. Misener, Medical Administrative Assistant to the Director General of Treatment Services, Department of Veterans Affairs, and Secretary of that Department's Pharmaceutical Committee, is relevant to the question of quality control as between large and small firms, inasmuch as the well-known firms are likely to be the large firms:

"MR. MACLEOD: Now, has the policy of the Department in ordering in generic names posed any problem as to the quality of the drugs which you have obtained? Perhaps I should say, resulted in any difficulties in relation to quality?

DR. MISENER: Naturally our doctors want to be assured that the drugs are proper quality before giving them to the patients. It is the policy to have newer drugs obtained from less known companies assayed or tested by the Food and Drug Division of the Department of National Health and Welfare. It is time consuming. Mr. Shaw can tell you more about this. Sometimes shipments have to be rejected due to low quality so it poses that problem, at least.

MR. MACLEOD: Yes, you do follow the practice of testing drugs which are purchased?

DR. MISENER: The least well known companies I think I would say."

(Hearing, pp.336-37)

8. Expenditures on Quality Control
in Relation to Value of Sales

Table XXIV of the Green Book shows for 27 drug firms the percentage relationship of expenditures on quality control to the value of net sales. The Green Book (p.143) noted that "there is little, if any, correlation between the value of sales and the amount spent on quality control". The distribution of expenditures on quality control for the 27 firms was as follows:

<u>Percentage of</u> <u>Net Sales</u>	<u>No. of</u> <u>firms</u>
nil	6
Less than 1 per cent	10
1.00 - 1.99	8
2.00 - 2.99	3

It was calculated by the Director that the average expenditure on quality control for the 27 firms amounted to 1.21 cents for every dollar of sales. It was pointed out in the Green Book that a very important factor affecting expenditures on quality control in Canada is the fact that many branches or subsidiaries of foreign companies import prepared dosage forms of certain drugs on which further expenditures for quality control would presumably be negligible.

From the evidence which was heard by the Commission it would appear that many firms would have difficulty in separating some costs of quality control from costs of manufacturing generally, as, in many cases, steps to insure quality enter into each stage of production until the drug is put in package form. On the basis of information received from 22 of the 27 firms reporting expenditures on quality control the Director calculated that such expenditures represented approximately 3.62 per cent of the cost of goods sold. The survey of drug firms made on behalf of the Canadian Pharmaceutical Manufacturers Association included information on quality control expenses in 1960 of 35 companies. The figures reported included amounts spent in Canada and amounts charged to Canadian companies by parent or affiliated companies outside Canada for the operation of quality control laboratories and to cover the costs of testing in outside laboratories. However, the figures did not include the cost of inspection staff and other techniques designed to control the manufacturing process required to produce a quality product. For the 35 firms the cost of quality control as described amounted to 4.2 per cent of total production cost in 1960.

The brief of Nordic Biochemicals Ltd. stated that the costs

of quality control, research and development accounted for approximately 9 per cent of its gross sales (Nordic brief, p.16; Hearing, p. 1406). On this question, Mr. Antoft, President of the company, testified as follows:

" . . . I should say this figure of 9 per cent is the direct cost that we can attribute directly to control and research activities. In a small organization such as ours there is a great deal of overlap of production personnel who may assist our control personnel so that this nine per cent is subject to revision upwards. We have [not] tried to break it down for our own purposes as we have no particular necessity to do so."

(Hearing, p.1406)

In the excerpts from the brief of Cyanamid of Canada Limited, reproduced in section 1 of this chapter, a distinction is made between the old concept of quality control consisting merely of testing finished products against certain standards and the modern concept bound up with all aspects of procurement, manufacturing, storage and shipment to customers. The brief also contained the following statement:

"Quite naturally, the percentage of the sales dollar spent on quality control will depend in very large measure on which of these two concepts of quality control are being used - the old or the modern. In many instances, the accounting techniques being utilized by the pharmaceutical industry have not as yet been developed to reflect adequately the true cost of the modern concept of quality control. These two factors must be considered in evaluating the tabulation submitted by the Director."

(Cyanamid brief, p.31; Hearing, p.1507)

CHAPTER VIII

THE INSPECTION OF DRUGS

1. The General Work of Inspection

The powers of inspection set out in the Food and Drugs Act are very broad⁽¹⁾. While, as a rule, their use is a matter of discretion, special provisions ensure a minimum of inspection with respect to the drugs listed in Schedules C, D and E. Accordingly no Schedule E drug may be sold, unless the batch from which it comes be deemed "not unsafe for use"⁽²⁾. This ensures the examination of a sample of every batch that is sold. However, according to Dr. Morrell:

" . . . Those drugs now are becoming less used. Originally that section was used quite a lot, because it included the organic arsenicals that were used in the treatment of syphilis for example, but the antibiotics have replaced these drugs, although there are a few of them still available, . . . "

(Hearing, p. 114)

As for the drugs set out in Schedules C or D, which are of the biological type and include the antibiotics for parenteral use, none may be sold, unless the premises in which they are manufactured and the process and conditions of manufacture be deemed suitable to ensure that the drug is "not unsafe for use"⁽³⁾. In effect, this means that no Schedule C or D drug may be sold, unless a licence is issued on a yearly basis after inspection of the premises, whether they are located in Canada or abroad⁽⁴⁾.

(1) Appendix B to this Report, Food and Drugs Act, s. 21.

(2) Ibid., s. 13.

(3) Ibid., s. 12.

(4) Appendix C to this Report, Food and Drug Regulations, C.03.001 (b), C.04.001 (c), C.04.006 and C.04.007.

Since the adoption of Bill C-3 in the course of the current session of Parliament, there is an absolute prohibition of the sale of the drugs listed in Schedule H⁽¹⁾. All drugs other than those designated in Schedules C, D, E and H are subject only to the general prohibition contained in sections 8 and 11 of the Food and Drugs Act. Under these sections, it is forbidden to manufacture, prepare, preserve, package or store any drug under unsanitary conditions or to sell any adulterated drug or any drug which was manufactured, prepared, preserved, packaged or stored under unsanitary conditions. With respect to the work of inspection carried out by the department, Dr. Morrell gave the following evidence:

"DR. MORRELL: We have authority to inspect at all levels, right down to the retail, but we do feel that it is more profitable, with the limited number of staff that we have, to pay attention mostly to the manufacturer, because we feel that if it is right when it starts, it has a fair chance of being right when it is used, having regard to shelf life etc.

MR. MacLEOD: You say manufacturer. Is that manufacturer of the prepared dosage form?

DR. MORRELL: Yes, that is the manufacturer of a prepared dosage form that I am thinking of."

(Hearing, p. 116)

"MR. MacLEOD: Do you carry out any inspections in countries outside of Canada?

DR. MORRELL: We do where it is licensed of course. If a company is licensed to manufacture a biological product in Canada he must be inspected at least once a year, and this is done too. Where there is no license provided you have no real authority to inspect a plant, in Italy for example, but by courtesy, and for other purposes they may be willing to receive your inspector, and we have sent an inspector to Italy to look at various pharmaceutical manufacturers."

(Hearing, p. 117)

(1) Appendix B to this Report, Food and Drugs Act, s. 14A.

"DR. MORRELL: . . . I think a year or so ago there were 300 or 400 inspections of pharmaceutical manufacturing plants made. Now, some plants are inspected much more frequently than others. If on going through a pharmaceutical plant we become satisfied and convinced that he has a good manufacture and analytical control, we feel there is no use going back there the next month or within six months. But there are some manufacturers whose facilities and personnel and perhaps attitude towards controls are not in our opinion all that they should be, so we do spend quite a bit of time in those plants and we may make three or four visits in a year to a plant of that sort. In that kind of a plant the inspector will surely take some samples from the production line for examination by the laboratory, and these he brings back. If it is a particular kind of test it will go to Ottawa, but generally they go to the laboratory for the region in which it is located, and they examine it for the active ingredients, for the availability, disintegration time of the pharmaceutical form, if it is a tablet, and they also look at the labelling. I don't know how many we did in the year 1960-61, but I think we had something under 3,000 samples the previous year, 2,700, 2,800. That is in the laboratory.

MR. MacLEOD: What sanctions do you apply or are you empowered to apply if the plant does not maintain a good standard?

DR. MORRELL: Well, we can prosecute, that is one; we can seize the product. We find that seizure is more effective than prosecution, and we have made quite extensive use of seizure. The penalties that we might get in a court would be perhaps not very adequate to convince him that he should mend his ways, but the seizure of his product is much more effective, I think."

(Hearing, pp. 121-23)

"MR. HUME: Your particular Directorate, I suggest to you, has not the best of public relations because I don't think generally the public appreciates the very important work that you would do for Canada. May I ask you this question with respect to the available staff that you have. Is it your opinion you have sufficient inspectors and lab people to adequately test and check drugs in Canada?

DR. MORRELL: No.

MR. HUME: Could you indicate whether or not this number you think should be doubled or tripled knowing the population and the demands upon your staff, I wonder if you could indicate to the Commission how adequate you consider your personnel, the number of your personnel rather?

. . .

DR. MORRELL: . . . oh maybe two or three times as many as we have, perhaps three times."

(Hearing, pp. 141-42)

In his evidence before the Commission (Hearing, pp. 138-41), Dr. Morrell said that, according to a verification made in 1960, around 30 per cent of the pharmaceuticals that were examined were found unsatisfactory in one way or another. However, in many cases, this was due to a slight difference between the actual and the stated potency. For instance, the permissible limits might be from 95 per cent to 105 per cent of the stated potency and the actual potency, only 92 per cent. Not being according to the regulations, such drugs had to be classified as unsatisfactory, but only five per cent or less were objectionable to the point that they had to be withdrawn. In regard to these drugs, Dr. Morrell stated:

"DR. MORRELL: . . . This five per cent or thereabouts might be dangerous to the point that a patient would not get the response that he should get and delay in changing the treatment or doing something that might be a danger to him, yes, but none that I know of - I know of none that I could find that were poisonous or would cause a man to be ill due to taking a dose of the drug."

(Hearing, p. 140)

To give this figure of five per cent its true significance, one must take into account that inspectors examine mainly those drugs which they have some reason to suspect. This is why Dr. Morrell expressed the opinion that those drugs which are unsafe for use in the technical sense explained above, might be substantially less than five per cent of all drugs offered for sale in Canada (Hearing, p. 141).

With respect to quality control as exercised by the pharmaceutical manufacturers, Dr. Morrell said the following:

"MR. MacLEOD: Do you find many drug manufacturers in Canada whose premises in your opinion are below what they should be?

DR. MORRELL: We find quite a number below the ideal. The number that are below what they absolutely should be is much smaller. This at the moment we have no authority to interfere with, but if we do find their products out of line we can take action against the product.

THE CHAIRMAN: Dr. Morrell, I might ask a little bit further on that point. You said you found a good many that are below the ideal.

DR. MORRELL: Yes.

THE CHAIRMAN: Do you find many that are ideal?

DR. MORRELL: Well, I don't know; maybe 5% or something close to it. They are very good.

THE CHAIRMAN: A very small percentage.

DR. MORRELL: Yes.

THE CHAIRMAN: Would those be chiefly large drug companies?

DR. MORRELL: Mostly, I think, yes.

THE CHAIRMAN: I want to ask you also, do your inspections enable you to give any considered judgment as to the control that is exercised, of quality, and so on, in the larger plants as compared with the smaller ones in this country, and also if you can tell me anything about that situation in other countries such as Italy, Britain and France. Does your inspection service enable you to reach a considered judgment?

DR. MORRELL: Well, I might make some remarks about it, sir, that might be of some value.

The control that is exercised by a pharmaceutical manufacturer will depend on the number of products that he is manufacturing and on the potency or the danger inherent in his products. One could imagine - and there are such manufacturers who are making such a few products of rather a simple and not particularly dangerous composition who would not require the same control procedures and personnel as a large manufacturer with several

hundred products coming out. There is a chance there, of course, for confusion unless everything is laid down and adhered to rather strictly in the procedure. So when you are looking at a plant you must consider what he is doing as well as how he is doing it.

Well, one could imagine a person making an aspirin or acetylsalicylic acid tablet and doing nothing else. That man would not require the controls that a man preparing Salk vaccine would and one rather simple control would be satisfactory and perhaps a complex control might not be necessary as in the latter case, the Salk vaccine case; you have to be very critical in that case. When you talk about plant inspection, it is a variable thing.

Now, some of the smaller companies, not putting out so many products, can do a reasonable job perhaps with less staff and less equipment than one who was putting out quite a variety and number of products. Now, all this has to be judged.

The ones that I referred to as being not in our opinion, frankly, satisfactory from a control standpoint are perhaps in the smaller group, fewer products.

As far as Italy is concerned, we saw - I wasn't there but the inspectors saw some very excellent plants and equipment and the personnel seemed to be very well qualified. But, on the other hand, I think he said that he had heard that there were over a thousand manufacturers there, and he only saw a few, and he is accustomed to this country and the United States and Britain and France, and some were not in his opinion as good, he would be rather uneasy about products coming from them."

(Hearing, pp. 123-26)

Finally, it must be stressed that, whatever is the extent of the inspection work carried out by the Department of National Health, in no case does the Department approve a drug or guarantee its quality. In an address made at the Consumers Association of Canada Conference held in Kingston in June 1962, Dr. C.A. Morrell explained as follows why this is not done:

"The Food and Drugs Act virtually does not permit the department to put a government stamp of approval on any food, drug, cosmetic or device nor to approve of any labelling, packaging or advertising. This is one of the reasons it is unlike some other federal legislation concerning foods.

The method employed by the Act and carried out in the Regulations is to make it an offence to do, or not to do, specific things. Since the law makes the omission or commission of specific [sic] acts a crime, the Food and Drugs Act is considered a part of Criminal Law and as Criminal Law it is within the authority of the federal government.

There is a law 'against murder' but the government does not give a certificate of approval to everyone who does not commit murder. The government does not officially approve of you and me because we obey the law. It is in fact our duty and responsibility to do so. If we do not and if, for example, we are discovered to be a thief or murderer and convicted of the crime, we must pay the penalty provided by law.

What I am saying, and I want to be perfectly clear about it, is that the persons preparing or selling foods, drugs, cosmetics or medical devices are responsible for their products and for ensuring that they meet the requirements of the Food and Drugs Act and they will get no official approval if they do.

It should be remembered also that a person who meets all the requirements of the Food and Drugs Act and Regulations in preparing or selling a product is not absolved in any way from his other responsibilities to the law or to the public, with reference to that product.

Another aspect of the law and its administration needs to be made quite clear and to be emphasized, particularly at this time. Many people believe that because of the existence of the Food and Drugs Act and the Food and Drug Directorate that everything found on the market that is a food, drug, cosmetic or device has been approved and found to be quite satisfactory in every way. This is not correct. There is no guarantee in this field any more than there is a guarantee that no crime will be committed just because there is a Criminal Code. The police cannot guarantee that there will be no robberies in Ottawa or anywhere else. The police are there to do whatever their facilities, abilities and numbers permit them to do, to detect and bring before the courts, those who commit robbery or other crime. This is what the Food and Drug Directorate is meant to do and does do, in respect to the Food and Drugs Act. I repeat, the members of the Food and Drug Directorate do all they can with the facilities, abilities and numbers at their disposal to detect violations

of the Food and Drugs Act and Regulations as well as of the Proprietary or Patent Medicine Act and the Narcotic Control Act and Regulations.

Indeed they do more than this in many ways. In the belief that 'prevention is better than cure' many employees of the Directorate spend a large proportion of their time advising manufacturers and others about the law and providing the industry with their opinion as to whether a new product or a label or a printed advertisement is likely to be in violation of the Food and Drugs Act or Regulations. There is no legal obligation for the Food and Drug employees to do this but it is felt that it will be in the interest of consumers if violations are prevented at the outset. It is my understanding that industry and business likes this approach because it helps to keep them out of trouble and saves them money in the long run. However, I will say again and again, that the offering of such solicited opinion, if no objection is taken, does not constitute approval of whatever article or activity, business or industry has submitted or proposed. Many times I have been told that 'Food and Drug approved' this or that. We never did any such thing.

. . .

Food and Drug [Directorate] is not a benevolent, all powerful all pervasive protector that acts as a personal, immediate guardian in respect to every mouthful of food and drink you take or every pill you swallow. It is a 'police' organization set up to 'police' a great number and variety of products and industries for the purpose of bringing about compliance with the terms of the Food and Drugs Act, the Proprietary or Patent Medicine Act and the Narcotic Control Act. The essential purpose of our policing is to make the manufacturers and dealers live up to these laws. No more and no less. The manufacturer must accept full responsibility for his products."⁽¹⁾

(1) C.A. Morrell, "Protecting the Consumer in the Fields of Food and Drugs", paper included in Canadian Consumers Problems, proceedings of a national conference sponsored by the Consumers' Association of Canada in co-operation with the Consumers Union of the United States, Inc. and held at Queen's University on June 20 and 21, 1962.

2. The Inspection of Imported Drugs

With respect to the inspection of imported drugs, Dr. Morrell gave the following evidence:

"MR. MacLEOD: Now, what about the inspection of the imports?

DR. MORRELL: Well, of course, that is done again by our inspectors and not always the same inspectors to which I have been referring as being plant inspectors.

We have a man who goes to the Customs in Montreal and one who goes in Toronto and also in Windsor and they look over the manifests and pick out products that are either known to them to be drugs or that are consigned to manufacturers known to them to be pharmaceutical manufacturers and they have instructions as to what to do.

We must limit our sampling to accommodate our laboratory staff. You cannot flood them with samples, which we could very easily do at the present time; so that we have chosen some products and some companies to watch more carefully.

This is done by the inspector who goes to the Customs. Now, in ports where there are no inspectors we have an arrangement with a Customs Inspector to notify us of shipments of drugs coming into the country. He holds them until one of our inspectors goes to see them or until he has a release from the Food and Drug Regional Laboratory or office.

MR. MacLEOD: Is it a fact then that your Directorate is notified of every importation of drugs into this country?

DR. MORRELL: No, I would not say it was a fact. A good many of them, but certainly not all of them.

MR. MacLEOD: What type of shipment might escape your attention?

DR. MORRELL: Well, our man goes to the Customs and it might be listed as a chemical, under a variety of names, and he may not consider that it is a pharmaceutical or basic pharmaceutical. He may miss it.

Certainly the Customs Inspectors are not familiar with all of the names of pharmaceuticals and I am sure they

miss - I am sure that we don't get all import samples.

MR. MacLEOD: Just to clarify that, are the arrangements such that they are intended to bring to your attention all such importations?

DR. MORRELL: Yes. I think so but they are not effective.

MR. MacLEOD: For the reasons you have just mentioned, amongst others?

DR. MORRELL: Yes, amongst others.

MR. MacLEOD: Of the ones you do learn about, you make a selection?

DR. MORRELL: Yes.

MR. MacLEOD: And actually take samples from those and have them analyzed and so forth?

DR. MORRELL: Yes.

MR. MacLEOD: What do you do with a shipment if it does not meet the requirements of the law?

DR. MORRELL: That is rather simple. At Customs we can refuse entry and it may then be shipped back to the country or to the exporter. That is easier to handle than when it is on the domestic market because then it is in the country and is the property of somebody in Canada and we have to seize them, not just refuse entry, but seize the product and take action on the basis of the seizure or prosecute, if we should feel that were necessary.

THE CHAIRMAN: Do you find it necessary to refuse entry on frequent occasions?

DR. MORRELL: No.

THE CHAIRMAN: Would you say about how many times a year it may happen; or does it happen as often as once a year?

DR. MORRELL: Yes. I think it would happen more often than once a year. I couldn't say how often.

MR. MacLEOD: Do you have any occasion to seize goods that have been imported into Canada that were not checked at the Port of Entry?

DR. MORRELL: Yes. I think I can say that because we know that the manufacturer himself has not produced them and that he has imported them and we get them in the final pharmaceutical form after he has processed them into a tablet or capsule and we have done quite a number of seizures at that level and these are imported drugs."

(Hearing, pp. 127-31)

3. Regulations Concerning New Drugs

Before a manufacturer may put a new drug on the market, several regulations⁽¹⁾ must be complied with. In these regulations, "new drug" is defined so as to include not only a new composition or dosage, but also a new usage for, and a new route of administration or method of manufacture of, an old drug⁽²⁾. Regardless of the fact that it may have been approved of in other countries, no new drug may be sold in Canada, unless a notice of compliance has been issued to the manufacturer⁽³⁾ and no such notice is issued, unless a new drug submission, including all the required information, has been filed with the Minister of National Health and Welfare⁽⁴⁾. With respect to this material, Dr. Morrell gave the following evidence:

"... Sometimes it is rather bulky and lengthy and we have provided now for a period of 90 days so that we can make a decision on the basis of the evidence in that time. Then we tell him whether the information he has submitted is adequate or inadequate, and if it is inadequate we tell him in what way it is inadequate."

(Hearing, p. 120)

(1) Appendix C to this Report, Food and Drug Regulations, C.01.301-C.01.307.

(2) Ibid., C.01.301.

(3) Ibid., C.01.306.

(4) Ibid., C.01.302.

Most manufacturing firms to whom a notice of compliance is issued choose to market their product under a brand name. Of course, other firms may import the basic drug from abroad, manufacture it into prepared dosage forms and market it either under its generic or another brand name, but this can be done only if a new drug submission is made and a new notice of compliance is issued. For, under the regulations, not only every new drug, but also every preparation of it has to be cleared by the Food and Drug Directorate⁽¹⁾. This requirement may be a serious barrier to a small manufacturer, for a new drug submission, according to Mr. Jules R. Gilbert, President of Gilbert & Company, is "a long . . . and expensive process" (Hearing, p. 2887). In his judgment, this is the reason why corticosteroids such as triamcinolone and dexamethasone and tranquillizers such as perphenazine, trifluoperazine, thioridazine and triflupromazine were available only under brand names. With respect to dexamethasone, the following information was given by Mr. Gilbert in his evidence:

"MR. FRAWLEY: Would you expect that if Dexamethasone, called Dexamethasone today, marketed in Canada as such, that you could buy it cheaper than Merck's price of \$9.40 for 30?

MR. GILBERT: I have offered it in export at \$35.00 a thousand.

MR. FRAWLEY: Merck's listed price is \$29.80 a hundred. All right, so much for that.

MR. GILBERT: I will add that at \$35.00 I [am] making a good profit."

(Hearing, p. 2891)

"MR. FRAWLEY: If Merck's or U.S.P. Decadron is simply Merck's brand of dexamethasone, which you say is what it is --

MR. GILBERT: Right.

MR. FRAWLEY: It is Merck's brand of dexamethasone that appears on the original package?

MR. GILBERT: Yes. It is not available under the generic name.

(1) Ibid., C.01.304.

MR. FRAWLEY: But it is available. It is available as Decadron and it is dexamethasone?

MR. GILBERT: That is right.

MR. FRAWLEY: Why can't it be sold as dexamethasone?

MR. GILBERT: They could sell it as dexamethasone if they want to, but only Merck can do that.

MR. FRAWLEY: That is right. Only Merck. He can sell it as either Decadron, the name that he has established, or he can sell it as dexamethasone?

MR. GILBERT: That is correct.

MR. FRAWLEY: And if dexamethasone is the generic name, the proper name, why couldn't you or Empire or anyone else that specializes in generics sell it and call it dexamethasone?

MR. GILBERT: The Food and Drugs Act takes care of that.

. . .

THE CHAIRMAN: You must have approval of your preparation?

MR. GILBERT: If I wanted to market it I must have approval from the Food and Drug administration.

THE CHAIRMAN: Not of dexamethasone but of your preparation of dexamethasone?

MR. GILBERT: I would probably market it under the name of dexamethasone.

THE CHAIRMAN: What you are getting is approval of your preparation of it?

MR. GILBERT: Yes."

(Hearing, pp. 2895-96)

A suggestion that the terms of reference of the Food and Drug Administration relating to the release of a new drug should be revised so that there could be a joint evaluation of toxicity and efficiency was put forward by Dr. Mark Nickerson, Professor and Head of the Department of Pharmacology and Therapeutics at the School of Medicine of the University of Manitoba:

"One other point I would like to make which I think is very important and which has been partially alluded to here, and that is the basis for the release of a new drug. Now, at the present time the terms of reference of the Food and Drug administration are that they are authorized to pass on toxicity. Many of the people in that organization I know realize that this is, in fact, an impossibility in isolation. We have already mentioned, and I think it can be said almost unequivocally, that there is no such thing as a non-toxic drug, when you consider the type of hypersensitivity that can occur, that any drug can damage. Now, the level at which you set permissible toxicity I think can only be determined in parallel with an evaluation of the effectiveness of the drug. If I were to come up with a drug today which would cure 50% of the cases of gastric carcinoma but would kill 20% or 30% of the patients who received it, it still should be passed, because at the moment they would all die. On the other hand, if I come up with a drug that more or less did the same things to stop a running nose, I cannot justify killing anyone. So it seems to me we have to revise our overall view of this and provide for a sort of joint evaluation of toxicity and efficacy to determine that when a new drug is released it will do more good than harm."

(Hearing, pp. 558-59)

It should be noted that, during the course of the current session of Parliament, an amendment was made to the Food and Drugs Act to provide specific authority for the enactment of regulations controlling the introduction to the public of new drugs⁽¹⁾. Furthermore, on December 7, 1962, a special committee of the House of Commons was "appointed to consider and report upon . . . the law and practices relating to the control of the introduction, marketing and use of drugs . . ." ⁽²⁾

(1) Appendix B to this Report, s. 24(1)(o).

(2) House of Commons Debates, Vol. 107, No. 51, December 7, 1962, p. 2427.

4. The Control of Advertising

As already pointed out, the advertising of drugs to the general public is prohibited: (a) with respect to prescription drugs⁽¹⁾; (b) as treatment, preventive or cure for the diseases listed in Schedule A to the Food and Drugs Act⁽²⁾; (c) with respect to a number of listed drugs when the single or daily dose recommended for human use exceeds specified limits⁽³⁾. Moreover no drug should be advertised in a misleading or deceptive manner⁽⁴⁾. Finally the label of a drug should carry specified indications⁽⁵⁾.

With respect to advertising to the general public, Dr. C.A. Morrell described as follows the supervision exercised by the Food and Drug Directorate:

"DR. MORRELL: . . . For example, the Broadcasting Act has a regulation^[6] which requires that all commercials for drugs and foods be submitted to the Department of National Health and Welfare for approval before they may be used on the air, and this of course will include patent medicines, as well as other drug products. They are examined in the Directorate. Perhaps 30,000 of these are examined each year, in English and French. Perhaps half of them maybe, half of them are drugs, so that we have an opportunity there to get a look at them and to criticize the advertisement before it is used.

In terms of written or printed advertising, we don't have that opportunity, and we must catch up with them. We subscribe to the newspapers and magazines, and look for advertising of pharmaceuticals or foods in those periodicals or journals.

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- (1) Appendix C to this Report, Food and Drug Regulations, C.01.044.
 - (2) Appendix B to this Report, Food and Drugs Act, s. 3(1).
 - (3) Appendix C to this Report, Food and Drug Regulations, C.01.021 and C.01.027.
 - (4) Appendix B to this Report, Food and Drugs Act, s. 9; Appendix F to this Report, Proprietary or Patent Medicine Act, s. 8(1)(d), (e) and (f).
 - (5) Appendix C to this Report, Food and Drug Regulations, C.01.004; Appendix F to this Report, Proprietary or Patent Medicine Act, s. 8(1)(c) and (d).
 - [6] Appendix J to this Report, Radio (TV) Broadcasting Regulations under the Broadcasting Act, s. 11.

MR. MacLEOD: What is the situation when you run across an advertisement which you feel is objectionable. Are you able to get the manufacturer simply to stop running the ad, or must you show there is some false claim?

DR. MORRELL: We have a book as a guide to manufacturers, to indicate the type of thing we will take objection to, so that they will know something about our attitude in advance, but still, looking at a newspaper or a periodical advertisement, we may find something objectionable, particularly perhaps one we consider is [a] violation of Section 3 of the Food and Drugs Act, which is a prohibition against the advertising of any food, drug, or cosmetics to the general public as a treatment, preventative, or a cure for any of the diseases or normal physical states named in a schedule to the Food and Drugs Act, and these include rather serious conditions, or conditions [for] which it is not advisable to encourage self-medication. They should have a doctor's diagnosis and supervision for treatment. Sometimes we come across advertising that infringes on this section, or it might infringe on something which we consider false, misleading, or deceptive, or likely to create an erroneous impression with regard to the drug. We usually don't prosecute immediately. We notify the advertiser that we consider the advertisement to be in violation, and in what way, and this gives him an opportunity to explain his viewpoint, but we ask him not to repeat the advertisement, at least until we have discussed the matter. The majority of them we have no difficulty with at all. They will do so, and I think in only one instance have we had a major court case on advertising^[1]. So that while we are always running behind trying to catch up, the situation isn't quite as bad as it may sound."

(Hearing, pp. 111-13)

[1] According to information conveyed to the Commission by Dr. C.A. Morrell in a letter dated August 27, 1962, the major court case referred to above is Rex v. A. Wander Ltd., 1948, 90 C.C.C. pp. 268-74. It should be noted that this case is concerned with the advertising of a food, not of a drug.

With respect to advertising to doctors and pharmacists, evidence was given to the Commission by:

(1) Dr. C.A. Morrell, Director of the Food and Drug Directorate:

"MR. MacLEOD: Do you exercise any supervision over the advertising of these drugs to doctors and professional people?

DR. MORRELL: Up to the moment, none, I would say.

Recently we have required certain information to be put into package circulars emphasizing the dangers of use of a particular drug; but beyond that we have not yet interfered in any way with advertising to the medical profession or to the pharmaceutical profession.

MR. MacLEOD: That is advertising appearing in the Canadian Pharmaceutical Journal or Drug Merchandising --

DR. MORRELL: Yes.

MR. MacLEOD: -- or the Canadian Medical Association [Journal].

DR. MORRELL: Yes, or direct mail advertising."

(Hearing, p. 134)

(2) Dr. Mark Nickerson, Professor and Head of the Department of Pharmacology and Therapeutics at the University of Manitoba:

"DR. NICKERSON: . . . A second point that was strongly recommended by the Committee on Pharmacy of the Canadian Medical Association just last year was that . . . all advertising should carry an indication of the toxicity of drugs. That is by and large available in medical journals and various places, but it was felt that the practising physician would benefit more by these if they were coupled in the material.

I think in my own mind that drug advertising to the physician probably should be re-evaluated in total. For a long time in both Canada and the United States there have been quite strict regulations on drug advertisements to the lay public because it was felt that they were not in a position to evaluate themselves the validity of the claim.

Advertising with the physician has been almost completely unrestricted, even to quite misleading information, because it was felt that the physician could stand between the advertising and the ultimate consumer.

I would like to submit that with a drug a day coming out and with the volume of advertising and journal literature that this is no longer possible, that the physician cannot stand between the advertising and the patient, and it may be that the advertising to the physician will have to be looked at more in the light of the advertising to the individual who cannot re-evaluate. I don't mean this to be impinging on the ability of the medical profession but simply they have been in my experience quite overwhelmed with the volume with which they have to cope.

. . .

THE CHAIRMAN: Doctor, have you any suggestions as to how this question of publicity to the doctors might be handled? It has been suggested that a hard look might be taken at it in view of the fact that the doctors are largely overwhelmed by the volume and they are not in a position to possibly evaluate all the drugs. I think you couldn't just prohibit all advertising to doctors.

DR. NICKERSON: No, I think you can't do that; I am not sure it would be desirable. Well, it would be a difficult thing at best. I think in essence it would amount to doing something similar to the investigations of toxicity, that is when a drug is proposed for distribution the manufacturer or distributor has to present evidence to show under what conditions it is produced, how much toxicity. I think it would be at least feasible to develop a system whereby the claims made by [sic, for] the drug are subjected to the same thing, that is satisfactory and controlled evidence that the drug would do this, that and the other thing."

(Hearing, pp. 557-60)

5. Proposed Revision of the Food and
 Drug Regulations

At the time of the hearings held by the Commission, extensive revisions of the Food and Drug Regulations were under consideration. With respect to the nature of the proposed changes, the

following evidence was given to the Commission by:

(1) Dr. C.A. Morrell, Director of the Food and Drug Directorate:

"MR. MacLEOD: Have you presently some rather extensive revisions to . . . the Regulations under consideration?

DR. MORRELL: Yes, there certainly are. The Minister hasn't seen them. They are under consideration. That is all I can say.

MR. MacLEOD: What are they designed to do?

DR. MORRELL: Well, they are designed to exercise much greater control over the manufacturing of pharmaceuticals for sale in Canada."

(Hearing, pp. 135-36)

(2) Dr. Mark Nickerson, Professor and Head of the Department of Pharmacology and Therapeutics at the University of Manitoba:

"DR. NICKERSON: . . . I think there is only one really satisfactory solution, and that is that we have to reach a position where any drug that goes on the market in Canada at least meets certain minimum specifications. The Canadian Drug Advisory Committee, of which I am a member, has drawn up with the Food and Drug Directorate a new set of regulations which involves recording the source of drugs, imported or not imported, and specific tests, and I think if the Food and Drug Directorate, if it did have adequate resources, or were given the adequate resources to carry this through, it would give reassurance that drugs on the market are up to standard, but I can see no real solution to the generic name promotional problem without having some basic assurance of these minimum specifications."

(Hearing, pp. 547-48)

"THE CHAIRMAN: With regard to the suggestions you made for variation in the methods followed by the Food and Drug branch, do you feel that these suggestions will assure reasonable accuracy of the drug available to the Canadian market?

DR. NICKERSON: I feel that they will, or at least will go a long ways in this direction. The one thing I don't know about from my own personal experience is the extent to which the Food and Drug Director at the moment has the facilities to carry them out. This might possibly require more personnel.

THE CHAIRMAN: Do you think you could say it would be quite impossible to undertake the thorough testing of every batch of drugs that comes out on the market?

DR. NICKERSON: Yes. This is the reason the advertising committee made the suggestion, that they will require analytical data, information of sources of raw material that went into the manufacture and provide also, when the Director feels necessary, for inspection of the facilities, and although it may still be a lot of work, I think it is more feasible to check records and analyses, and so on, than it is to do the actual testing of all drugs and so on."

(Hearing, pp. 560-61)

CHAPTER IX

TARIFFS AND SALES TAX

1. Rates of Customs Duties Applicable to Drugs

It is necessary to inquire about the effect, on the prices of drugs sold in Canada, of tariffs on imports of drugs or materials used in their preparation. On this subject, the Green Book (pp.27-28) reproduces a list of the principal tariff items under which drugs are imported and the rates of duty⁽¹⁾. However, in using this list, one must keep in mind section 5 of the Customs Tariff. When the conditions stated therein are fulfilled, any importer of non-liquid medicines who is entitled to the benefits of the British Preferential Tariff is also entitled to a discount of 10 per cent on the amount of duty. By way of illustration, the net rate for item 220(i), under such circumstances, would be 15 3/4 per cent instead of 17½ per cent. It must also be taken into account that by virtue of the emergency measures taken by the Canadian government in June 1962 the British Preferential and the GATT rates applicable to the goods specified in tariff item 711 have temporarily been increased by 5 per cent ad valorem⁽²⁾.

(1)

The Green Book does not reproduce tariff item 220 in its entirety. To complete the quotation, the following material should be inserted on page 28 before the paragraph relating to "Drugs, pill-mass and preparations":

	British Preferential Tariff	Most-Favoured- Nation Tariff	General Tariff
Any article in this item containing more than forty per cent of proof spirit shall be rated for duty at per gallon and	\$3.00 30 p.c.	\$3.00 30 p.c.	\$3.00 30 p.c.

(2)

The Canada Gazette, Part II, Vol.96, June 24, 1962, p.14.

An analysis of the list referred to above shows that some drugs or materials used in the preparation of drugs may be imported into Canada duty free. Most drugs however are subject to duties. According to the country of origin, the rates are normally in this ascending order: British Preferential, GATT, Most-Favoured-Nation and General Tariff. With the exception of Hong Kong, members of the British Commonwealth of Nations and British Territories are entitled to the British Preferential Tariff. The most-favoured-nation tariff applies, among others, to the United States and most European countries including France, Italy and Holland. Finally, whenever there are some rates determined under GATT, they apply to the members of the Geneva Agreement and also to the countries entitled to the benefits of the most-favoured-nation tariff.

Under the British preferential and the most-favoured-nation tariff, one factor which affects the rates with respect to single drugs is whether or not the item is "of a kind not produced in Canada". Thus, under the most-favoured-nation tariff, the rate, in the case of a drug not produced in Canada is 15 per cent and, otherwise, it is 20 per cent. With respect to the interpretation that should be given to the expression "of a kind not produced in Canada", Mr. J. S. Deachman, appraiser for the Department of National Revenue, gave the following evidence:

"MR. DEACHMAN: With respect to drugs which are not specifically provided for under the Tariff the kind is the determining factor with respect to tariff classification. That means it has got to be the exact chemical. . . . With a chemical it would have to be a chemical of the same quality. When dealing with the application of a dumping duty it is class or kind which is a broader interpretation. That is where competitive chemicals and competitive drugs come into the picture."

(Hearing, p.36)

With respect to mixtures of drugs, there is a special provision in item 220 for "Drugs, pill-mass and preparations, not including pills or medicinal plasters, recognized by the British or United States Pharmacopeia, the Canadian Formulary or the French Codex as official". By reason of this provision, some medicinal or pharmaceutical preparations, which otherwise would be covered by item 220, are covered by item 220a⁽¹⁾. Another factor which affects

(1)

As Tariff item 220a is not reproduced in the Green Book, it is shown in Appendix G to this Report.

the rate with respect to compounds is the per centum of proof spirit which they contain. The presence of alcohol also has the effect of excluding imports from the benefits of the ten per cent discount provided for in section 5 of the Customs Tariff.

2. Valuation for Duty

Whenever any duty ad valorem is imposed on any goods imported into Canada, the value for duty is not less than

"the fair market value, at the time when and place from which the goods were shipped directly to Canada, of like goods when sold

- (a) to purchasers located at that place with whom the vendor deals at arm's length and who are at the same or substantially the same trade level as the importer, and
- (b) in the same or substantially the same quantities for home consumption in the ordinary course of trade under competitive conditions"⁽¹⁾.

Sometimes the ascertainment of the fair market value in the country of origin gives rise to some difficulties. Mr. J. S. Deachman, in his evidence, pointed out that many drug manufacturing companies in Canada are subsidiaries of companies in the United States and may secure supplies of basic chemicals or processed drugs from the parent company. If the American company purchased a chemical in large quantities and then transferred a portion to its Canadian subsidiary, the valuation for duty would be based on the market price of the quantity supplied to the Canadian company. If a market price did not exist for such a quantity then the price per unit paid by the American company would be advanced by 5 per cent, for customs valuation purposes. If the chemical purchased by the American company went through a process of manufacture before being supplied to the Canadian subsidiary, the value for duty would be advanced up to 50 per cent to cover added material, labour and overhead. If the drug entered Canada as a finished product in bulk for packaging the

(1)

Customs Act, s.36.

valuation for duty would be the original cost of material increased by up to 75 per cent and if the product was imported in packages in finished form but unlabelled, for labelling in Canada, the advance in cost would be up to 100 per cent. Such valuations are made under section 38 of the Customs Act when there is no prevailing market price for the particular quantities or forms in which materials are supplied by the parent company in the United States to its Canadian subsidiary (Hearing, pp.39-47).

In the event that a dutiable drug imported into Canada is invoiced at less than the full market value in the country of origin, a special dumping duty is applied whenever the article is "of a class or kind made or produced in Canada".⁽¹⁾ With respect to the interpretation given to these words, Mr. J. S. Deachman's evidence is as follows:

"MR. MACLEOD: Now would you say something about made in Canada rulings in respect to drugs? Is it the particular drug or the class of drug that counts?

MR. DEACHMAN: It is pretty much class. For instance, you mentioned tranquilizers. We wouldn't distinguish, if there is one tranquilizer made in Canada we say class. Take Salk vaccine. When that originally came on the market it was unique, and we said it is a class. When it comes to sedatives, we don't make a distinction.

MR. MACLEOD: Although a particular drug contained in a particular product which is not made in Canada, it would nevertheless be classified made in Canada?

MR. DEACHMAN: It would be classed as a class made in Canada for dump-duty purposes, but not in accordance with Tariff Item 211 [Tariff Item 711]. There is a distinction.

MR. MACLEOD: If it was priced to the Canadian buyer at what you consider a fair market value in the country of origin, it would pay a lower duty?

(1)

Customs Tariff, s.6.

MR. DEACHMAN: Yes, if it was not made in Canada, but when we come to the dump-duty, a particular drug would have to conform to in general whether it was a class or kind, made in Canada, for dump-duty purposes we would say it is a class."

(Hearing, pp.44-45)

The effect of the special dumping duty is to bring the cost to the importer up to the fair market value in the country of origin. As the importer would not benefit from any lesser price, it would be expected that the exporter would establish his selling price so as to obviate the payment of dumping duties by the importer. Situations of this kind usually arise when a Canadian subsidiary makes purchases from a parent or related company abroad. For this reason, the Commission agrees with the following statement made by the Director in the Green Book:

"... To the degree that the price charged by a foreign parent company to a Canadian subsidiary approaches the trade price in the country of origin, profit is taken by the parent rather than by the subsidiary. In an extreme case, such as that referred to in the letter quoted in Chapter III [p.29] above, the Canadian subsidiary may sell at a loss, but it is obvious that the regular profit on the particular product had already been taken by the parent company. This means that profits of Canadian subsidiaries are not an accurate indication of the actual profit resulting from the sale of imported drugs; they reflect the earnings of the Canadian subsidiary only and do not reflect any profit previously taken by the parent company."

(Green Book, pp.223-24)

3. The Federal Consumption or Sales Tax

The 8% consumption or sales tax imposed by section 30 of the Excise Tax Act (see Appendix H to this Report) and the 3% Old Age Security tax collected with it under section 10 of the Old Age Security Act (see Appendix I to this Report) apply to all drugs except the following mentioned in Schedule III of the Excise Tax Act:

"SCHEDULE III

Charitable, Health, Etc.

Adrenocorticotrophin (ACTH); Cortisone; Insulin; Radium;
Articles and materials for the sole use of any bona fide
public hospital certified to be such by the Department of
National Health and Welfare, when purchased in good faith for
use exclusively by the said hospital and not for resale;

. . .

Liver extract for use exclusively in the treatment of
anaemia;

. . .

Vaccine for use in the prevention of poliomyelitis, and
material for use exclusively in the manufacture thereof;

. . . "

As stated by the Director in the Green Book:

" . . . The exception in favour of hospitals only applies
if the drug is not resold by the hospital and this seems to
have been the reason why many hospitals formerly charged
patients a flat daily rate which included the supplying of
necessary drugs. If the patient was charged separately for
drugs, the sales tax would apply. Since the cost of most
drugs supplied by hospitals will now be part of the general
operating cost of the hospitals and will be paid for under
the various hospital plans, presumably virtually all drugs
sold to hospitals will be free of sales tax."

(Green Book, p.27)

Thus, except for those sold to hospitals and the few
others mentioned in the above schedule, all drugs are subject to
a combined tax of 11%. Such a tax applies whether the goods are
produced or manufactured in Canada or imported from abroad. It
is calculated on their sale price or, when payable by a licensed
wholesaler with respect to an imported article, on the duty paid

value. The latter is defined by law as being "the value of the article as it would be determined for the purpose of calculating an ad valorem duty upon the importation of such article into Canada under the laws relating to the Customs and the Customs Tariff whether such article is in fact subject to ad valorem or other duty or not, plus the amount of the Customs duties, if any, payable thereon." (1)

Section 21 of the General Excise and Sales Tax Regulations provides an alternative method of computation and payment of tax for use by any licensed manufacturer. According to this method, goods are taxed on values relating to the same level of trade and this is the level at which transactions take place between manufacturers and wholesalers. For instance, when taxable goods are sold direct from manufacturers to retailers, the tax is applied to the prices at which the same goods are sold to wholesalers or, if there is no such market, prices to retailers are discounted to take into account that some of the services actually provided by the manufacturers are usually performed by wholesalers. It is obvious that, under such a method, the amount of tax that is actually paid with respect to a particular drug represents less than 11 per cent of the price charged to retailers and a still smaller proportion of the retail price. As will be shown in Chapter XV, 40 per cent and 16 $\frac{2}{3}$ per cent off the retail list prices are common discounts on sales to wholesalers. In such a case, the excise tax represents about 5 per cent of the retail list price, for, if the latter is \$1.00, the net price to the wholesaler is 50 cents and this includes an excise tax of about 5 cents.

As a matter of course, the administrative costs of collecting and remitting the tax incurred by those who pay the tax form part of their total costs which they seek to recover in the prices they charge.

(1)

Excise Tax Act, s.29.

4. Provincial Sales Taxes

In some of the provinces where there is a provincial sales tax, some drugs may be subject to it. This is not true of Saskatchewan and New Brunswick where the exemption applicable to them is general (1). However in Ontario, Quebec and British Columbia, (2) drugs are exempt from the tax only when sold on prescription.

(1)

Revised Statutes of Saskatchewan (1953), c.61, s.6; Revised Statutes of New Brunswick (1952), c.213, s.10 as amended by s.19 of c.25 of the Statutes of 1953.

(2)

Statutes of Ontario (1960-1961), c.91, s.5; Revised Statutes of Quebec (1941), c.88, s.12; Revised Statutes of British Columbia (1960), c.361, s.5.

CHAPTER X

DUPLICATION AND PREMATURE PROMOTION OF DRUGS

1. Doctors, Drugs and Drug Promotion

Reference is made in Chapter VIII to the supervision exercised by the Food and Drug Directorate over the advertising of drugs by mass information media: that is to say the press, radio and television. In the present chapter and the four which follow, attention is given to the promotion of drugs by drug companies. However it is necessary to keep in mind that ethical drugs, with which this report is particularly concerned, are not advertised through these mass media. With respect to them, there is no advertising to the general public and most advertising and promotion take the following forms: advertisements in professional and trade journals, direct mail and distribution of samples to physicians and pharmacists and dissemination of information through sales representatives of the manufacturers, usually referred to as detail men, calling upon medical practitioners, pharmacists and hospitals.

Any opinion or conclusion about the overall value of the drug manufacturers' expenditures on advertising and promotion as well as on research must take account of the whole interrelated process by which the drug industry has developed, produced, promoted and sold a considerable stream of new drugs since World War II. The value to society of the industry's research, advertising and promotion is related ultimately to the value that these drugs have had in the treatment of disease and in the promotion of the health of the population. On the question of the benefits of the stream of drug innovations, the Commission must necessarily, in view of the fact that it is not made up of qualified physicians, rely upon the opinions of medical practitioners recorded in the transcript of the hearings before the Commission or expressed elsewhere.

A general evaluation of the stream of drug innovations and the role played in it by drug promotion is given in the article "Doctors, Drugs and Drug Promotion"⁽¹⁾ by Dr. Mark Nickerson, Professor and

(1) The Canadian Medical Association Journal, Vol. 80, April 1, 1959, pp. 520-24; reproduced in the Green Book, pp. 285-90.

Head of the Department of Pharmacology and Therapeutics at the University of Manitoba, and his colleague Dr. J.P. Gemmell, Associate Professor of Medicine, which was reprinted in full in the Green Book (pp. 285-90). Complete reproduction of the article in this report is unnecessary, but it may be useful to summarize some of its main ideas.

The article states the authors' opinion that relatively few new products contribute substantially to medical progress. The stream of new drugs has become so great that the majority of busy practitioners no longer attempt personally to evaluate the data on new agents even when such data are available. The material prepared and distributed by pharmaceutical manufacturers must be carefully evaluated as advertising. The authors assert that the chemistry of medical compounds has advanced to the point where generally it is possible for a group of good chemists to produce on request a compound closely related to a known drug and having comparable activity. Usually this agent does not have important advantages over its predecessor and may be somewhat inferior. A mixture may be easily and rapidly prepared to meet sales requirements. These multiple drug preparations expose patients to an increased number of toxic reactions, particularly of the sensitivity type. It is unnecessary for a company to await the development of a really superior product before entering the competition. Substantial profits frequently can be made from even a very inadequate product long before any clear evaluation of effectiveness is possible. Every drug has some toxicity and it is much more important to know the types of toxicity which may occur. Advertisements rarely carry this information. Reports of toxicity are slow to appear. Mixtures of drugs preclude independent evaluation of the effects of the constituents and adjustments of the relevant dosages to the needs of specific patients.

Questions on the article referred to above asked by the representative of the Director brought out the following answers from the co-authors and from Dr. Nathan Schechter, practising physician and Chairman of the Pharmacy Committee of the Ottawa Civic Hospital:

(a) from Dr. Gemmell:

"MR. MacLEOD: Just as a general question, we haven't referred in detail to your article which was included in the material which you submitted to the Commission. Does that article now reflect your views, or have you modified them in any way?

DR. GEMMELL: Not in the least, except that I would be inclined to make some of the statements a little stronger.

MR. MacLEOD: Your first point is I think that very few products, despite the ballyhoo that is associated with their introduction, make substantial contributions, or are really wonder drugs.

DR. GEMMELL: That is right.

MR. MacLEOD: And do you feel that is so, of the many new drugs and combinations coming on the market, only a few are really significant advances?

DR. GEMMELL: That is right.

MR. MacLEOD: I think you have covered pretty well the difficulty of the practitioner in keeping up with the material. A little bit later on in your article you speak of the imitators. Is it your experience that when a drug of some significant value comes on the market, that it is likely to give rise to a number of imitators?

DR. GEMMELL: If it is at all possible for the chemist to produce it within patent arrangements, which I am not familiar with, and in some cases in spite of patent regulations.

THE CHAIRMAN: You mean it is possible to form slightly different combinations with a different trade name?

DR. GEMMELL: It is identical. For example, diutel clorthazide [sic, Diuril (chlorothiazide)] is followed closely by hydrochlorthazide [sic, hydrochlorothiazide], which is followed again closely by hydro fluorthazide [sic, hydroflumethiazide]. There are very many in the steroid field.

THE CHAIRMAN: Those three you have described have identical uses with practically identical results?

DR. GEMMELL: Yes, the dose may be a little different, but the result is identical."

(Hearing, pp. 524-25)

(b) from Dr. Nickerson:

"MR. MacLEOD: You were associated with Dr. Gemmell in preparing an article which appeared in the Canadian Medical Association Journal under the title 'Doctors, Drugs and Drug Promotion'?

DR. NICKERSON: Yes sir.

MR. MacLEOD: And just generally, do you still subscribe to the views which you, in association with Dr. Gemmell, put forward in that article?

DR. NICKERSON: Yes sir."

(Hearing, pp. 538-39)

(c) from Dr. Schecter:

"MR. MacLEOD: Did you read in the Canadian Medical Association Journal an article that is referred to as an appendix 2 in the, what we have been calling the blue book [sic, Green Book] here, that is Doctors, Drugs and Drug Promotion.

DR. SCHECTER: Yes sir.

MR. MacLEOD: You read that in the Canadian Medical Journal?

DR. SCHECTER: I read it quite a while ago. As a matter of fact it was an article I analysed for one of our meetings.

MR. MacLEOD: Would you agree with the views expressed by the authors of that article?

DR. SCHECTER: Completely."

(Hearing, p. 266)

2. Duplication of Drugs

Figures are available with respect to the types of new pharmaceutical products introduced on a national scale in the United States during the years 1948-59. As shown below in Table 11, of the 5727 new pharmaceuticals introduced during this period, 2795 were mixtures of two or more active ingredients, 1356 were drugs already on the market in other forms of administration, 1085 were new brand names for existing drugs and only 491 were new chemical entities.

Table 11

New Pharmaceutical Products Introduced on a
National Scale, United States,
1948-1959

Year	New Chemical Entities	Duplicate Products New Manufacturers	Compounded Mixtures	New Forms of Administration	Total
1948	36	142	221	102	501
1949	40	147	202	170	559
1950	28	100	198	118	444
1951	35	74	212	120	441
1952	35	77	202	170	484
1953	48	79	226	97	450
1954	38	87	255	108	488
1955	31	90	282	96	499
1956	42	79	280	66	467
1957	51	88	261	96	496
1958	44	73	253	109	479
1959	63	49	203	104	419
Total	491	1,085	2,795	1,356	5,727
Annual Average	41	90	233	113	477

Sources: Facts about Pharmacy and Pharmaceuticals,
New York, N.Y., Health News Institute, 1958
and de Haen, Paul, "1959 Pharmaceutical
Products Parade", Drug and Cosmetic Industry,
Vol. 86, No. 2, February, 1960, p. 161.

Table 12 shows the nature and source of the new chemical entities introduced during the year 1959. Of the total of 63, 23 were derivatives of known drugs, 11, new salts of old products and only 29, truly new drugs. Of these 29 new original products, 13 were developed in Europe and 16 in the United States.

Table 12

Source and Nature of New Chemical Entities
Introduced to the Pharmaceutical Market,
United States, 1959

	Developed in United States		Developed in Europe		Total	
	No.	Per cent	No.	Per cent	No.	Per cent
New original products	16	37	13	65	29	46
New salts of old products	10	23	1	5	11	17
Derivatives of known drugs	17	40	6	30	23	37
Total	43	100	20	100	63	100

Source: "1959 Pharmaceutical Products Parade", Drug and Cosmetic Industry, Vol. 86, No. 2, February, 1960, p. 161.

This situation was commented on as follows by Mr. Paul de Haen in an article published by Drug and Cosmetic Industry:

"It is interesting to note that of the 43 new chemical entities developed in the United States, 27 were based on past knowledge representing either derivatives of previously known structures or new salts of old products. It therefore appears that, although Americans are primarily interested in what the future holds and seem to place little emphasis on past developments, the majority of new products introduced during 1959 could not have been developed in the United States if past history had not led the way. This statement is not meant to imply that the development of derivatives or new salts of previously known compounds is less valuable from a therapeutic or commercial point of view. The observation primarily indicates, however, a direction of attitude and suggests a pressure toward being 'productive' or following the 'bandwagon.' It is sometimes easier to improve than to originate or, perhaps, as Alexis de Tocqueville said over one hundred years ago Americans are more addicted to practical than to theoretical science. But on the other hand such breakthroughs as the antibiotics, cortisones and chlorothiazides have brought the American pharmaceutical industry revenue far exceeding its expectations."⁽¹⁾

(1) Paul de Haen, "1959 Pharmaceutical Products Parade", Drug and Cosmetic Industry, Vol. 86, No. 2, February 1960, p. 161.

On the problem of the duplication of drugs, Dr. J. B. Ross, Minister of Health, Province of Alberta, read as follows from the brief submitted by the government of that province:

"It does not seem practical or desirable to suggest that educational or governmental bodies be asked to perform clinical evaluation of all drugs produced. In the United States, from 1948 to 1959, there were 491 new clinical entities introduced. These 491 items, when handled by the trade, resulted in 1,085 duplicate products by other manufacturers, 2,795 compounds of two or more active ingredients, and another 1,300 previously known drugs were re-introduced under new brand names.⁽¹⁾ ⁽²⁾ Numerous modifications of this type may be expected whenever the new drug becomes truly popular. Chlorothianzide [sic, chlorothiazide] introduced as Diuril in 1958 is an example. It was a commercial success to the point that in 1959 there were introduced four similar drugs with small changes in the molecule. Clinical experience with these and another three analogues have been published recently.⁽³⁾ ⁽⁴⁾ ⁽⁵⁾ ⁽⁶⁾ ⁽⁷⁾ Some are more potent than the original but this means only a smaller (not necessarily cheaper) pill is required to produce the same desirable and undesirable effects. Increased potency is of no value without a difference in the 'therapeutic ratio', i.e. the ratio of the dose producing desirable effects to the dose producing undesirable effects. Although there is no definite evidence of a differential in the therapeutic ratio or other features of the action of these congeners, either alone or in combination with other drugs, they are now under active promotion. Reports in the literature are nearly as confusing as the advertisements.⁽⁸⁾ ⁽⁹⁾

If there should be important advantages associated with the use of a particular one of these related chemicals, it is not at all certain that such advantages could be recognized quickly. The task of evaluating scientifically the clinical usefulness and the drawbacks of a specific drug is usually a difficult and time-consuming undertaking. In the case of the thiazide preparations, it is difficult to visualize any program to evaluate these drugs that will effect [sic] the atmosphere of competitive promotion.

References

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- (3) Edelstein, S.G., Flescher, R., Morrison, R.S., Howard, F.A. and Chalmers, T.C. - Controlled Double-Blind Evaluation of Hydroflumethiazide and Hydrochlorothiazide - New England J. Med. 264:207 (February 2) 1961.
- (4) Symposium - New Diuretics and Antihypertensive Agents - Current Therap. Research 2:237 (June) 1960.
- (5) Beckman Harry - Yearbook of Drug Therapy 1959/60 - Chicago, Ill. Yearbook Publishers 1960.
- (6) Fallis Norma E. and Ford, Ralph V. - Current Concepts in Therapy. Limitations in the Use of Thiazide Diuretics - New England J. Med. 263:296 (August 11) and 504 (September 8) 1960.
- (7) Rosembloom, Stanley E. et al - Technique of Controlled Drug Assay, Comparison of Chlorothiazide Hydrochlorothiazide and Placebo in Hypertensive Patient - New England J. Med. 264:164 (January 26) 1961.
- (8) Stills, David D. - More Drugs Die Young as People Live Longer - Am. J. Pharm. 131:407 (November) 1959.
- (9) Sheps, Mendel C. - Amer. Journal Public Health 647:654 (May) 1961."

(Government of Alberta brief, pp. 2-3, 6-7;
Hearing, pp. 860-61)

The above quotation confirmed the following statements by two representatives of the medical profession:

(a) by Dr. Nathan Schechter, practising physician and Chairman of the Pharmacy Committee of the Ottawa Civic Hospital:

"DR. SCHECTER: . . . This is a very difficult problem, to try to assess the real value of all the new drugs coming out, because a great many of them are duplications of those in existence or just small chemical changes, like Dr. Modell says, to horn in on the sale. So it is difficult for any publication to keep up to date."

(Hearing, p. 255)

"DR. SCHECTER: . . . For example meprobamate, a tranquilizer, is the generic name for a host of tranquilizers such as Frenquil⁽¹⁾, Equanil and Miltown and so on. If we have meprobamate as a generic name, we do not have to print 67 different other names. We might after meprobamate mention a few trade names, those being either the earliest ones that came into the picture or where we consider the pharmaceutical company the most reliable in its field.

THE CHAIRMAN: Did you mean when you referred to meprobamate and then gave the other names, is that the trade name of it?

DR. SCHECTER: Yes.

THE CHAIRMAN: That they are practically the same?

DR. SCHECTER: They are identical.

THE CHAIRMAN: Those drugs with the several names are identical?

DR. SCHECTER: They are identical, yes.

The thing is that if one learns the generic name for drugs one does not have to learn all the duplications, all the various brand name products."

(Hearing, pp. 259-60)

"MR. MacLEOD: Quite satisfactory. Now, what do you feel, Doctor, about the number and variety of dosage forms and duplications to some extent at least of drugs that are on the market?

DR. SCHECTER: Of course, there is too many of the same type of drug; each company claims that theirs is the best. Obviously that cannot be, so that we have to select the drug we are going to use in individual cases. Certainly there is very much duplication, minor changes. . ."

(Hearing, p. 265)

(b) by Dr. C.H. Reardon, practising doctor in the City of Halifax and Member of the Legislative Assembly in Nova Scotia:

(1) The term "Frenquil", as here quoted, seems to be an error. Frenquel is a brand name not for meprobamate, but for azacyclonol.

"DR. REARDON: . . . If you get a group of drugs all with the same action and have the same results, then you don't have to know them all. All you have to know is the few you know are efficient and what they do. Certainly there is some time lag between the time they come out and the time you know all about them.

I contend the time lag doesn't make any difference to the patient. A lot of the new drugs are rehashes of one you already have. They don't make a tremendous difference. You can take your time and catch up with what is new.

THE CHAIRMAN: Do you mean one drug company brings out a new drug that is really a new drug, not just a modification of something else?

DR. REARDON: Sure.

THE CHAIRMAN: And then other companies produce drugs which are sometimes identical, sometimes slightly different but not very different in their operative value.

DR. REARDON: The effectiveness is pretty much the same.

THE CHAIRMAN: So you could prescribe a drug made by A Company or B Company or C Company or D Company knowing whichever company you get it from, it would do practically the same thing for your patient, is that it?

DR. REARDON: Yes.

THE CHAIRMAN: Drugs that are identical will be sold under different names.

DR. REARDON: I am sure that is true.

THE CHAIRMAN: In some cases there might be a slight modification?

DR. REARDON: Yes."

(Hearing, pp. 383-84)

3. Variations in Products Ostensibly the Same

Two preparations with the same generic name may act differently on the same patients, even if the route of administration is the same, whether oral, parenteral or topical. Some evidence referred to in section 2 of chapter VII shows that a given drug, when manufactured by a number of different producers, may display variations, even when the different manufacturers' products all meet the minimum requirements of the U.S. Pharmacopeia and section 4 of the same chapter deals with the importance of administering an accurate dose of certain drugs to patients suffering from particularly critical diseases. Moreover the formulation of drugs "into various dosage forms may modify profoundly the onset, intensity and duration of physiological response, the correct dosage for the patient, the incidence and intensity of side effects, and the stability of the drugs"⁽¹⁾. In this respect, The C. Ph. A., in its submission to the Commission, subscribed to the views expressed by Dr. Gerhard Levy, of the School of Pharmacy of the University of Buffalo, and Dr. Eino Nelson, of the School of Pharmacy of the University of California Medical Center, in an article [Exhibit T-15] from which the following excerpts are reproduced:

"Pharmaceutical Formulation and Therapeutic Efficacy

There is a mistaken belief among many that the active constituent as a chemical entity is the sole basis for the pharmacological effectiveness of a pharmaceutical product. It is the purpose of this review to show that the physiological response to the administration of a given drug product is frequently a function of both the pharmaceutical formulation of the particular dosage form as well as of the active ingredient. Certain variables related to pharmaceutical formulation will be discussed with respect to the manner in which they may modify therapeutic response in the hope that the examples cited may lead to the recognition that the choice of dosage form and of brand can be just as important as the choice of the actual therapeutic agent.

In general, differences in therapeutic efficacy among different generically identical drug products, while sometimes caused by lack of stability or by contamination,

(1) Gerhard Levy and Eino Nelson, "Pharmaceutical Formulation and Therapeutic Efficacy", Journal of the American Medical Association, Vol. 177, No. 10, September 9, 1961, pp. 689-91 at 689.

are most frequently due to differences in the rate at which the active ingredient or ingredients become available for absorption. This may modify the onset, intensity, and duration of the desired physiological response. Furthermore, the efficiency, the biological availability (e.g., the completeness of absorption), as well as the incidence and intensity of side effects and toxic reactions from the drug may be affected.

A dramatic example illustrating differences in intensity of action of a drug as a result of dosage form modification has been given by Lozinski. His company found it desirable to increase the physical size of their bishydroxycoumarin (Dicumarol) tablets to facilitate breaking the tablets for administration of half doses. Patients who switched from the smaller to the new larger tablets required larger doses in order to maintain prothrombin levels in the therapeutic range. Laboratory studies undertaken to explain this difference indicated that the dissolution rate of drug from the large tablets was slower than from the old tablets. The tablets were reformulated to increase this rate, and these were then used to replace the stocks of older tablets in retail and hospital pharmacies. A surprising turn of events occurred. It became apparent that some patients who had their prescriptions refilled with the newest tablets showed prothrombin levels below the therapeutic range and in some, bleeding occurred. The company alerted all physicians concerning the more intense therapeutic effect of the new bishydroxycoumarin tablets and urged that all patients on anticoagulant therapy with their brand of bishydroxycoumarin tablets be retitrated for their requirements. It is quite likely that no 2 manufacturers' brands of bishydroxycoumarin tablets will act alike in therapeutics, and it is conceivable that a change from a slow release brand to a fast release brand might even result in death if the necessity for retitration is not recognized.

. . .

Suspensions

Ordinarily, suspensions of slightly soluble drugs might be thought to be identical in action regardless of the brand used, since this type of dosage form usually provides high absorption availability. However, the availability of a drug for absorption and the efficiency of the preparation depends on the size of suspended particles. This is illustrated by a comparative study of

sulfadiazine suspensions. A fine particle suspension gave more rapid absorption with higher maximum blood level and greater area under the blood level versus time curve than a similar suspension containing somewhat larger particles. (The area beneath the blood level versus time curve is a measure of efficiency of the preparation in terms of total drug available for absorption.) In this same work with sulfadiazine, smaller standard errors in blood levels occurred when the finer crystals were given, indicating a more predictable response in therapy with this drug.

. . .

Ophthalmic Preparations

Soehring and co-workers have studied the effect of vehicle composition on the action of aqueous solutions of ophthalmic drugs. They found that the vehicle may induce changes in the cornea, resulting in increased drug penetration. The absorption of drugs across the cornea is also a function of the length of time during which the medication is in contact with the tissue. It is possible to enhance the response to ophthalmic solutions by increasing the viscosity of such preparations through addition of methylcellulose or certain other polymeric substances. These tend to depolymerize on storage, a process which is accompanied by a decrease in the viscosity of their solutions. In such cases, depolymerization may be minimized by proper manufacturing procedures, formulation, and choice of polymer type.

. . .

Parenteral Products

One of the most generally appreciated examples of the effect of variation in formulation on the therapeutic response to parenteral products is insulin. The onset and duration of action of this drug can be varied by changing the particle size of the crystals, by the choice of pH, and by varying the concentration of certain additives. The mere replacement of an acetate buffer by a phosphate buffer changes a long-acting insulin to a short-acting one.

. . .

Ointments

Shelmire has pointed out that there may be a marked difference in the clinical effectiveness of a drug in different vehicles. He could show differences between aqueous, oily, nonvolatile water-miscible, oil-in-water and water-in-oil vehicles by determining the rate at which a water-soluble dye, an oil-soluble dye, vitamin A, and salicylic acid diffused from the various vehicles to the skin surface. However, marked differences in efficacy were noted even within a given vehicle type. . . .

. . .

Suppositories

The type of base used in the preparation of suppositories may have a marked effect on absorption of the active ingredient. For example, it has been reported that while salicylate levels from the administration of acetylsalicylic acid in one type of base were nearly the same as those obtained after oral administration of the same dose, another type base gave only about 50% of this level. . . ."⁽¹⁾

With respect to this matter, the following evidence was given by two witnesses who appeared on behalf of The C. Ph. A.: Mr. J.C. Turnbull, its General Manager and Secretary-Manager, and Professor A.W. Matthews, its first Vice-President and Dean of the Faculty of Pharmacy of the University of British Columbia:

"MR. WHITELEY: Is there any criterion which distinguishes between those products such as the one referred to yesterday that the pharmacist wouldn't regard as being the same and those preparations which he would regard as being in the same class?

. . .

DEAN MATTHEWS: I think perhaps I might cast a little light on Mr. Whiteley's question . . .

. . .

(1) Ibid., pp. 689-91.

In the example Mr. Turnbull is quoting from, this drug [1] does have a very specific effect on a very specific physiological function, and therefore a minute difference in the rate of absorption or the rate of dosage would have a distinguishable effect, whereas other ingredients which have a more general effect would not be influenced nearly as much by the small difference in the size of the tablet or in the amount of filler used, and therefore the pharmacist would need to keep things of that nature in mind, as well as the actual physical differences which Mr. Turnbull has commented upon.

MR. TURNBULL: There are other problems involved which are related to this overall question. These include the problem of duplication and the resultant multiplicity of drug preparations which have a high degree of similarity. The multiplicity of similar drug preparations cannot be considered as wholly undesirable, provided that the ethics of the companies involved in their production are without question and that the medical and pharmaceutical professions are aware of the merits of the preparations and of the companies. . . ."

(Hearing, pp. 2383-89)

4. Premature Promotion of Drugs

Closely related to the duplication of drugs is the premature promotion of numerous variations of the original preparation. On this subject Dr. Nathan Schechter gave the following evidence:

"DR. SCHECTER: . . . and I think that there has been too, too rapid a spread of these drugs without proper evaluation. I think if there were less of them coming out, giving us more chance to evaluate them and so on, it would be much better.

They say we now have almost more drugs than we have diseases for them."

(Hearing, p. 265)

[1] The drug referred to is Dicumarol. In the excerpt from the article by Dr. Gerhard Levy and Dr. Eino Nelson, quoted earlier, this drug is given as an example to illustrate differences in intensity of therapeutic action as a result of dosage form modification.

This point was developed more fully in the brief of the Government of Alberta, as follows:

"Despite exceptions, premature and excessive promotion of drugs, inadequate investigation and unnecessarily confusing duplication are common. New products are accepted more rapidly and become obsolete more rapidly. Generally today a new product either soars to popularity within the first few months after it is launched on the market or else the promotional program fails and the product is doomed to mediocrity. The sales people try to rush each new drug on to the market in the hope of a successful run. Such pressure works against deliberate objective evaluation of the drug in clinical medicine. It produces emphasis on the maximum speed consistent only with reasonable assurance of relatively low toxicity, on a well chosen name for the product and a successful promotion campaign which may produce a best seller for a year or two. Should it appear eventually that a product is really a valuable addition to the physician's armamentarium so much the better. Some of the responsibility for the failure of a large part of the clinical effectiveness of drugs to meet scientific standards must be ascribed to the urgency of the drug marketing methods.

. . .

In Alberta, as a result of past experiences, where precipitate promotion interfered with objective clinical evaluation of new products, most clinician consultants refuse to undertake evaluation unless a clear undertaking is made that no promotion of a product is contemplated until adequate investigation to allow valid conclusions is completed. In the past, it has happened that active promotion of a drug with its attendant ballyhoo has been initiated in the United States within a few weeks after an investigation has been started at the University Hospital in Edmonton at the suggestion of the drug firms. This inevitably results in the investigator becoming an unwitting party to the promotion."

(Government of Alberta brief, pp. 2-4;
Hearing, pp. 858-62)

With respect to the above excerpt, the following evidence was received by the Commission from Doctor J.D. Ross, Minister of Health, Province of Alberta and Dr. F.B. Rodman, Assistant Clinical Professor of Therapeutics at the University of Alberta:

"DR. ROSS: . . . Dr. Wilson, who is Professor of Medicine at our University Hospital, sir, has on occasions been asked to carry out clinical evaluations of drugs, only to find that before he can even get it under way to a proper evaluation and determination of the efficacy of the drug, it

was being actively promoted for sale to the public through the general medical profession.

THE CHAIRMAN: Yes, but the paragraph [the last paragraph of the previous quotation] refers to it being advertised and promoted in the United States while investigation was going on in Canada.

DR. ROSS: Of course, sir, there is no boundary to the advertising that goes on in the drug trade.

THE CHAIRMAN: I quite understand that. I was wondering whether you have clear evidence that it had not been previously studied and investigated in the United States.

DR. ROSS: I think, sir, that that question could be better answered by Dr. Rodman, who has taken an active part in the investigation of some of these drugs."

(Hearing, p. 862)

"THE CHAIRMAN: One other question that I asked while Dr. Ross was reading the brief. He referred to the active promotion of a drug with its attendant ballyhoo, and a programme being initiated in the United States within a few weeks after an investigation started at the University Hospital in Edmonton. My question was whether you knew that no such investigation programme had been carried on in the United States prior to the ballyhoo in the United States, or whether they were relying on what was started in Edmonton as a basis for the ballyhoo?

DR. RODMAN: This is like the case of the individual who burns himself on the stove once. He usually does not do it again. I know that Dr. Wilson and others associated with him found the same thing that I personally found. I was visited by a representative who assured me that this was a new product and they were looking for a primary investigation. In my innocence I agreed to do so and started a programme, only to find two months later that not only were there five other sources in Canada investigating it, the publications were coming in large quantities from the States.

I think in all fairness though, that we ourselves walked into situations like that in Edmonton. I don't think we do that any more. We ask too many questions, and I would also say in all fairness to the drug firms that they now send their directors around, and these are honest and

fair men, and no longer does one as a rule need to worry too much about this type of thing.

The type of investigation that they are doing is carefully outlined, and with a few questions one can soon ascertain whether this is a primary research that is really desired or merely a promotional campaign to acquaint you with the product.

THE CHAIRMAN: I was getting at whether there had been basic or primary research made previous to the promotion for sales purposes, and your comments indicate that they were asking a dozen or more research groups to conduct what they thought would be primary research into the same drug?

DR. RODMAN: From my own experience I would say I undertook primary investigation of one drug at the request of a Canadian firm, but I didn't know, and I take it as my error, that I didn't search the literature, although I think it was not in publication to within a short time of beginning work. Another company in the United States was working on this material. That is not unusual with a new drug.

THE CHAIRMAN: That is there was some research?

DR. RODMAN: Definitely and I feel that the firm that asked me in this particular case were aware of it.

THE CHAIRMAN: But it is far more objectionable from your point of view I suppose for them to start ballyhooing the sale on your research before it is completed? Is that the situation?

DR. RODMAN: It meant you just wash out two months' work.

THE CHAIRMAN: But you wouldn't want to be party to a promotion for sale of something which you were investigating but had far from completed your research because your results might be very different?

DR. RODMAN: That is right sir.

. . .

"MR. MacLEOD: Are not you yourself able to express an opinion that will be of value to the Commission on the statements made at page 2 [of the submission of the Government of Alberta]. You don't have to go to any authorities outside your own experience, do you? Aren't you in a position to see when drugs come on the market and whether there is a background of literature on their effects available, and so on?

DR. RODMAN: Yes, definitely.

MR. MacLEOD: In your opinion, based on your own experience, are those statements correct that are made there?

DR. RODMAN: I think so sir."

(Hearing, pp. 900-04)

5. Physicians' Difficulties in Keeping Informed on Drugs

To appreciate the physicians' difficulties in keeping informed on drugs, cognizance must be taken of the number of drugs in current use and the proportion of them which are relatively new. With respect to the situation in the United States, some figures are available for a not too distant past. According to a paper read by Dr. Ethan Allan Brown, a Boston physician, at the 103rd Annual Meeting of the American Medical Association held in June 1954:

"An advertisement for a recent edition of the 'Red Book' which lists all of the 140,000 medicaments handled by pharmacists and available to physicians for patients, states that '14,000 new drugs' were issued by drug manufacturers in 1953. In actuality, there were few really new drugs. The number given represents some truly introduced for the first time, such as new salts, new derivatives, and, in many cases, new mixtures (as an antibiotic with an antihistaminic). Some of these drugs represent a new form or type of administration or merely a new packaging of an old drug. These old drugs are, however, not too old, in that 90% of those most commonly prescribed have been discovered within the last 25 years."⁽¹⁾

(1) Dr. Ethan Allan Brown, "Problem of Drug Allergy", The Journal of the American Medical Association, Vol. 157, No. 10, March 5, 1955, p. 814.

If one excludes new packagings of an old drug and also truly new products marketed only on a regional scale, the number of new pharmaceuticals, as shown in Table 11, is 450 for the year 1953.

Moreover, according to a study of the prescription market, new products are accepted more rapidly and become obsolete more rapidly. Here are the conclusions of this study:

"'Explosive' is a more apt description of the 1958 prescription market than is 'dynamic', a term frequently used to characterize it. For during 1958, there truly was an explosion in the profitable group of prescription products - those appearing 5 or more times per 10,000 prescriptions.

More products, far more, dropped out of this group and many more products entered it than during any previous year. In both cases, the products involved were younger than those observed in other years.

Two forces are responsible for this trend:

First, the keen competitive research race to produce new and more effective drugs to alleviate suffering and lengthen the life span.

Second, modern 'crash' promotional programs that create almost immediate acceptance and prescription demand.

We are in the tenth year of studying the prescription market. Each year, we scrutinize more than a quarter million prescriptions. This has been possible only through the cooperation of the pharmacy schools - their deans, faculty supervisors, and hundreds of students - and pharmacists in twenty-three states or populous areas.

Each year, we have observed a parade of products into and out of the group of products prescribed 5 or more times per 10,000 prescriptions. In 1958, the parade was longer. (Hereafter, the products prescribed 5 or more times per 10,000 prescriptions will be referred to as the 400 Group.)

. . .

Here are our conclusions:

1. As pharmaceutical research expands, the turnover of products leaving and entering the 400 Group increases.
2. This turnover in 1958 was much higher than we have ever observed in our ten-year study of the prescription market.
3. The products entering and leaving the 400 Group are younger, indicating more rapid obsolescence.
4. Despite this increased turnover, the number of products in the 400 Group remains constant. This is phenomenal since there are 400 to 500 products introduced each year. There are said to be about 1,200 products under more or less heavy promotion. But, in nine years, the number prescribed at this high frequency has ranged only between 393 and 413. For 1958, it was 408.
5. The products dropping out are replaced by products with much higher prescription frequency and dollar volume.
6. About the same number of companies are represented annually by the products that drop out and enter the 400 Group.
7. Products which remained at this prescription frequency through 1957 and 1958 accounted for the bulk of the prescription market (about 73.5 per cent of the dollar volume), but their prescription frequency rate and dollar volume showed a decline from 1957. Many of these products are headed for obsolescence.
8. In 1958, a higher percentage of products introduced during the year reached and maintained a frequency of 5 or more per 10,000 prescriptions. In the past years, we have observed that only 3 per cent to 4 per cent of these new products reached this frequency during the year of their introduction. However, in 1958 this percentage was more than doubled, based on the published report of Mr. Paul de Haen, who listed 370 new chemical entities and combinations for the year.
9. Our studies substantiate the belief of many that, as effort and expenditures for pharmaceutical research increase and as crash promotional programs continue

to publicize the results of this expanded research, we can anticipate even greater annual turnover of prescription products with acceleration in their rate of obsolescence.

10. While the rapidity of obsolescence was slightly greater in certain therapeutic groups, nearly all therapeutic groups contributed to this obsolescence."⁽¹⁾

While lower than for the United States, figures for Canada show that the task of keeping informed on drugs is far from being a sinecure for Canadian doctors. In a lecture⁽²⁾ before the Consumers Association of Canada Conference held at Queen's University in June 1962, Dr. C.A. Morrell, Director of the Food and Drug Directorate, gave the following information:

"During the last eleven years, 1883 new drug submissions have been received. There have also been many hundreds of supplements to new drug submissions We know that there are somewhat more than five thousand drug stores offering for sale an estimated 25,000 kinds of tablets, capsules, elixirs, tinctures, solutions, ointments and other dosage forms of medicines and drugs. . . ."

All physicians who appeared before the Commission agreed that, years after his graduation, the practising doctor no longer possesses an adequate knowledge of the drugs in current use unless he has sought sources of information on the new drugs constantly being developed and brought to the market. In this respect the following evidence was given by:

(a) Dr. Nathan Schechter, practising physician and Chairman of the Pharmacy Committee of the Ottawa Civic Hospital:

"MR. MacLEOD: Doctor, you have mentioned the terrific increase in the number of drugs. I would like you to tell the Commission your own personal experience. Do you yourself find it hard to keep up with the developments?"

(1) David D. Stiles, "More Drugs Die Younger as More People Live Longer", The American Journal of Pharmacy, Vol. 131, No. 11, November 1959, pp. 407-409.

(2) Dr. C.A. Morrell, "Protecting the Consumer in the Fields of Food and Drugs", paper included in Canadian Consumers Problems, proceedings of a national conference sponsored by the Consumers' Association of Canada in co-operation with the Consumers Union of the United States, Inc. and held at Queen's University on June 20 and 21, 1962.

DR. SCHECTER: Yes, it is difficult. In my position as Chairman of the Pharmacy Committee and the idea of having to turn out a new edition of this pharmacopoeia every two years, it is an extremely difficult problem to try to keep it up to date, and this Vademecum International we frequently get supplements regarding new drugs to paste into the pages of different companies. So it is a very difficult problem to keep pace with it and to ascertain particularly the toxic effects of various drugs, which is very important."

(Hearing, p. 249)

(b) Dr. C.H. Reardon, general practitioner and Member of the Legislative Assembly of the Province of Nova Scotia:

"MR. MacLEOD: Doctor, in your practice do you have any problem arising out of the number of new drugs that come on the market?

DR. REARDON: I have no problem.

MR. MacLEOD: Are you able to keep yourself up to date on them?

DR. REARDON: Yes.

MR. MacLEOD: What sources of information do you rely on for information about new drugs?

DR. REARDON: Well, I think mainly doctors rely upon medical journals for their main sources of information, and another very valuable source of information comes from the drug companies themselves through the media of detail men, through the media of advertising.

MR. MacLEOD: Now, taking the medical journals, Doctor, do you find that there is any time lag there, that you may have to wait a while to get an authoritative article on new drugs in medical journals or anything like that?

DR. REARDON: The time lag is not so important. You generally can pick up any information that you really want on new drugs just by enquiring in the proper place. You can enquire of your medical school and of your specialist confreres who know perhaps a little ahead of you some of these things. I don't believe that the time lag in new drugs is really a very important item in general practice.

MR. MacLEOD: Just referring to what you said a moment ago do you feel you are in a better position being located in Halifax where there is a medical school and a number of specialists, do you feel that you have a more adequate source of information being located in Halifax than you might have if located elsewhere?

DR. REARDON: No, it may be a little more convenient for me to obtain the information, but certainly any doctor practising in Nova Scotia can get information by picking up the telephone and calling one of his friends in Halifax, one of his confreres somewhere else. I don't think that is so important.

MR. MacLEOD: So that you feel that you have adequate knowledge and sources of knowledge to use all the new drugs to the best advantage?

DR. REARDON: Adequate sources of knowledge, and they are there if anyone wants to get them."

(Hearing, pp. 366-68)

"THE CHAIRMAN: You mentioned you found no difficulty in keeping up with the new drugs coming along. We are still pretty green in this field. We only started last week. One of the witnesses last week indicated there were, perhaps, a couple of hundred new drugs coming on the market every year. I was wondering if the work involved didn't take a considerable part of your time?

DR. REARDON: The main point I want to make was the source of information available.

THE CHAIRMAN: Yes.

DR. REARDON: For anybody who wants to find out, it is there. No one would attempt to keep up with every single new drug on the market. . . ."

(Hearing, p. 383)

(c) Dr. James William Reid, specialist in internal medicine, practising in the City of Halifax:

"MR. MacLEOD: Taking the general head, first, do you in your practice find any difficulty in keeping up with the new drugs, the developments in the drug field?

DR. REID: Yes, it is very difficult to keep up with it, largely because it is so deeply into chemistry, new chemistry that it is not easy for the practising physician to keep abreast of it. We sometimes accept the new preparations for their clinical value, but most of us trained in our time, on the older pharmacology, we knew the drugs and could actually prepare a good many of them ourselves. This is new therapeutics, and all these new chemical preparations only a chemist could be entirely familiar with the actual drug itself. We can only be familiar with its clinical behaviour in the treatment of the sick."

(Hearing, p. 386)

(d) Dr. Mark Nickerson, Professor and Head of the Department of Pharmacology and Therapeutics at the University of Manitoba:

DR. NICKERSON: Yes, well, I think undoubtedly the best source of information is in the actual original data in medical literature. That is, how many cases and in what way, and controlled conditions as compared to something else. Not infrequently these data are not available, at least with the drug's introduction into the market, and with the average practising physician I think we have to recognize that it is simply impossible for them to obtain this. If you recognize that there is one new product per day coming on the market, even when the literature contains all the information, to do thorough search and reach a firm conclusion is a matter of two or three full days of work. In other words, it would be close to impossible, if the physician had nothing else to do except read these. I might state an example that the medical college which is composed of full-time people in the drug field, we don't think that any one man can keep up with the material. . . ."

(Hearing, p. 546)

(e) Dr. J.P. Gemmell, Associate Professor of Medicine at the University of Manitoba:

"THE CHAIRMAN: With regard to this vast mass of material that comes in to a doctor's office, are you able to tell us what becomes of it? Do the doctors attempt to read it - I gather it is impossible to read it all - what do they do with it? Do they attempt to go through it pretty carefully?

DR. GEMMELL: Well, sir, it is almost impossible to keep up with even the properly published literature. . . ."

(Hearing, p. 516)

Four of the five witnesses quoted above admitted having great difficulties in keeping up with the developments in the drug field. It is clear that the majority regarded the present situation as unsatisfactory but no definite suggestions were made for improvement. Two dangers are apparent: one that some physicians may accept promotional claims which have not been sufficiently established and the other, that a really effective agent may be overlooked by a busy physician in the mass of information which is sent to him by drug companies. With respect to the situation in the United States, Dr. Walter Modell of Cornell University Medical College, wrote as follows:

" . . . Already it is abundantly clear that the medical profession is one of the losers. It is gradually giving over its initiative in choosing drugs for its patients to the detail man because it cannot deal with the plethora of new drugs expertly, safely, effectively. Obviously, the public is an even heavier loser.

What will happen when, as it eventually must, physicians refuse to gamble with their patients' lives and health or an enraged public demands that such gambling stop? Certainly the winning streak of the pharmaceutical industry will come to an abrupt end, but the rebound may well be excessive and may lead to unhealthy cynicism on the part of physicians and a state of therapeutic nihilism.

If the pendulum then swings as far in the other direction, as pendulums do, the medical profession will tend to lean more and more on the handful of proved, established drugs such as morphine, penicillin, and digitalis, about which it can read substantial unbiased statements in textbooks, about which it will hear nothing from the detail man, and about which it will see nothing illustrated beautifully in drug house brochures, but on which it knows it can depend because of the accumulation of an enormous body of useful experience. And in this counterploy, surely important discoveries of our time will be overlooked and lost. How long before the public, medicine, and the drug industry are the losers to this type of general reaction?"⁽¹⁾

(1) Walter Modell, M.D., "The Drug Explosion", Clinical Pharmacology and Therapeutics, Vol. 2, No. 1, January-February 1961, p. 3.

6. Druggists' Difficulties in Keeping Informed
on New Drugs

The difficulties of retail druggists in keeping abreast of current developments in the drug business were described as follows by two members of the pharmaceutical profession who appeared as witnesses before the Commission:

(1) Mr. Alfred Pepper, retail pharmacist from Regina and President of The Saskatchewan Pharmaceutical Association:

"MR. MacLEOD: Are new products a problem to you? Do you find it difficult to keep up with the new products coming out, involving stocking problems and so forth?

MR. PEPPER: There are stocking problems, but we have arrangements with most of the better-known manufacturers that they will automatically ship us a very small quantity. If we do not immediately index and file the information on this new product, then we may be lost. We take each one as it comes and learn something about it and have the informational material readily available. There is no problem at all.

MR. MacLEOD: How many new products would you have to deal with in an average month?

MR. PEPPER: It is easy to start an argument amongst us here. I would say six or eight.

MR. MacLEOD: Well, I suppose that could be gathered by going through the Canadian Pharmaceutical Journal for a year and looking at the monograms which I believe are prepared by Dean Hughes of Toronto.

MR. PEPPER: I should have confined my answer to six or eight that I stock. Probably, as you say, there may be a dozen or so in there, and many of the monograms in there are actually of old products which were not previously listed.

MR. MacLEOD: And some of them of course would be simply new dosage forms of a product with which you were already familiar, but at any rate your estimate is six or eight?

MR. PEPPER: Yes, that we handle."

(Hearing, pp. 840-41)

(2) Mr. Douglas Denholm, Registrar of the Pharmaceutical Association of the Province of British Columbia:

"MR. MacLEOD: I was just wondering. There seems to me to be a little conflict there between the problem which you have touched on and dealt with, I thought very fully in your brief, about the pharmacist keeping up with current information and advising the doctor. How can a busy man, who is twelve to fourteen hours on the job find time for outside reading sufficient to keep up with the multiplicity of new drugs?

MR. DENHOLM: As the length of time that he works or is on duty in his pharmacy lengthens, certainly the opportunities for such perusal of current literature and so on would be more difficult.

MR. MacLEOD: Is keeping up with new drugs a problem for the druggist, and perhaps you can speak of this, having been a practising pharmacist yourself?

MR. DENHOLM: In what respect sir?

MR. MacLEOD: Just keeping fully informed of the new drugs that come out?

MR. DENHOLM: Yes, it is indeed sir. This requires time to keep abreast of the developments."

(Hearing, pp. 1270-71)

CHAPTER XI

COST OF ADVERTISING AND TRADE PROMOTION

1. Relation of Advertising and Promotional Expenditures to Value of Sales

One feature of the pharmaceutical manufacturing industry is that outlays on advertising and trade promotion constitute a considerable percentage of the value of net sales. This is shown in Table XXIV of the Green Book which presents inter alia an analysis on a percentage basis of 27 selected firms' expenditures on advertising and trade promotion, research and quality control in relation to net sales for the year 1959. While there is no need to reproduce Table XXIV in this report, there is some value in pointing out certain of its outstanding features. As shown below in Table 13, arithmetic means of the percentages given in Table XXIV for each type and also for the total of advertising and promotional expenditure for the 27 firms have been calculated. It is emphasized that these averages are based on the percentage figures for each company and are thus not weighted by the sales of the individual companies.

Table 13

Percentages of Advertising and Promotional Expenditures
by 27 Firms in Relation to Net Sales for the Year 1959

<u>Type of Expenditure</u>	<u>Percentage of Net Sales</u>
Detail men and salesmen	14.94
Advertising in journals, etc.	1.95
Co-operative advertising	0.03
Direct mail	3.66
Samples	3.57
Other	0.77
Total	24.92

Source: Green Book, pp.108-10

As shown in Table 13, 27 firms spent on the average during 1959 an amount slightly less than 25 per cent of their net sales on advertising and promotion. Figures for 1960 were presented to the Commission by the Canadian Pharmaceutical Manufacturers Association and resulted from the answers to a special questionnaire which had been sent out at the request of the C. Ph. M. A. At the time this questionnaire was prepared, the Canadian Pharmaceutical Manufacturers Association had 54 members, of which 40 gave replies which were used in tabulating the results. Those companies probably accounted for about 91 per cent of total sales of pharmaceuticals by Canadian companies in 1959 (Hearing, pp.3049-51). Schedule 3 of this "Compilation of Results of Special Questionnaire" shows that in 1960 the percentage relationship of selling and advertising expenses on human pharmaceuticals to net sales of human pharmaceuticals for these 40 companies was 29.2 per cent. The percentage relationship of expenditures on selling and advertising on all products to net sales of all products was 26.7 per cent. These figures for 1960 for 40 firms tend to confirm the order of magnitude of the percentage figures presented by the Director in the Green Book for the 27 firms for the year 1959.

Table XXIV of the Green Book indicates considerable variation in the percentage of net sales spent by the individual firms upon advertising and promotion. The minimum and maximum percentages of net sales were 10.2 and 51.55 per cent.

The most important form of expenditure on advertising and promotion, that on detail men and salesmen, showed great variation between firms, ranging from a minimum of 4.61 per cent to a maximum of 39.31 per cent of net sales. For all individual firms except one, expenditures on detail men and salesmen were higher and generally very much higher than expenditures on any other form of advertising and promotion. In the one exception, expenditures on detail men and salesmen were exceeded in importance by the expenditures on direct mail. The firm with the highest expenditure on advertising and promotion was also the firm with the highest percentage expenditure on detail men and salesmen. It is also of interest that this firm spent nothing on direct mail and the costs of journal advertising made up most of the rest of its advertising and promotional expenditures.

The percentage of net sales spent on direct mail advertising varied greatly, from nil to 13.6 per cent of net sales. In the case of the firm with the highest ratio, expenditures on direct mail constituted over half of its total expenditures on advertising and promotion. Sixteen of the 27 firms had expenditures on direct mail amounting to less than 4 per cent of net sales.

Expenditures on samples varied from nil to 11.01 per cent of net sales. In the case of the firm with the highest percentage, cost

of samples made up almost one-third of its total outlay on advertising and promotion. Expenditures on samples amounted to less than 2 per cent in the case of 6 firms, between 2 and 3 per cent for 5 firms and between 3 and 4 per cent for 7 firms. The following comments on this variation were made in the brief of the Canadian Pharmaceutical Manufacturers Association:

"The tables on pages 108-110 of the green book show a considerable variation in the percentages of sampling costs to sales. We are reasonably certain that the higher percentages reflect more costly products such as the antibiotics. And these product samples are the very ones which the doctor will keep in his bag for night and emergency calls. Doctors do use samples, and it would hardly be practical to expect the physician to buy these products himself."

(Association brief, p.67; Hearing, p.1964)

The Green Book, p.115, notes that:

". . . There was a wide variation in the expenditures reported by particular firms, but the figures show, and this is a matter of common knowledge, that the large ethical drug firms spend proportionately more than do small firms. These large firms employ numerous detail men and are able to launch massive campaigns to introduce new products. . . . "

On this point, the following comments were made in the brief of Cyanamid of Canada, Limited:

"It is stated on page 115 of the Statement that the large ethical drug firms spend proportionately more than do small firms on advertising. We suggest that there is a good reason for this, namely, that large companies usually are those with original products. It is these products which require the greatest effective communication with the medical profession and the drug trade."

(Cyanamid brief, p.48; Hearing, p.1537)

2. Interrelationship of the Various Kinds of Advertising and Promotion

The drug manufacturing companies use several methods of advertising and promotion, apparently in the hope that doctors will learn about their products and particularly about their new products from at least one of the sources. This point was dealt with as follows in the brief of the Canadian Pharmaceutical Manufacturers Association:

"This triumvirate of pharmaceutical communications comprises within itself a unique method of ensuring that the doctor learns of a new discovery, and keeping him aware that the discovery is available. Generally, these three sources of information complement each other. A doctor is an extremely busy man. At given periods, he may not have the time to see a detail man, read a direct mail piece, or study his favourite medical journal. But as these three sources appear before him at different times, the chances are that he will at least learn of the new product from one of the sources. Which one, cannot be determined in advance, particularly when you are attempting to reach thousands of doctors as soon as possible.

For this reason, many companies use all three means simultaneously with the hope that each doctor will at least learn of the new product from one source. This, however, is by no means the rule. Some companies do no direct mail advertising whatever on the grounds that detail men are the best means of providing complete information to the doctor, and the fact that a large percentage of direct mail is discarded.

Other companies believe that direct mail is an efficient yet economical method of advising the doctor of the product. These firms point out that while a good percentage of direct mail may be discarded it is still the least expensive means of communication, costing as it does but a few cents per doctor. . . . "

(Association brief, pp.58-59; Hearing, pp.1934-35)

It is abundantly evident from Table XXIV of the Green Book that the various firms apportioned their advertising and promotion budgets in different manners. One firm, for example, spent more than half of its total budget for advertising and promotion on direct mail and something more than one-quarter of it on the expenses of detail men and salesmen. In contrast, another firm spent nothing on direct mail, over three-quarters of its total advertising and promotion budget on the expenses of detail men and salesmen, and a significant amount on advertising in journals.

While the emphasis placed on various marketing methods differs from one firm to the other, the Commission also heard evidence that some manufacturers have changed their marketing methods over a period of time. Mr. R. B. Thompson, Manager of the Medical Products Department of Cyanamid of Canada Limited mentioned some instances in the following excerpt from his evidence:

"MR. THOMPSON: It is not unusual for a competitor to adopt a practice which has been proven successful by someone who has experimented in this industry. Marketing methods have been subject to great change over the years. There have been philosophies in this industry that the best way to sell drugs is by a sales force unaided by advertising. Such a company was the Upjohn Company at one time.

MR. FRAWLEY: Now, Mr. Thompson . . .

MR. THOMPSON: In the opposite extreme as already stated, I suggest you look at Smith, Kline & French, a very successful company. They built their business on direct mail and general advertising alone. Over the years these two companies have changed their methods. Now you can hardly tell them apart. They have learned from each other's experience, I suppose."

(Hearing, pp.1664-65)

3. Expenditures on Detail Men

For the drug industry as a whole, expenditures on the activities of detail men and salesmen, as shown in Table 13, constituted by far the most important form of advertising and promotion in 1959 and the same was the case in 1960 according to the survey made by the Canadian Pharmaceutical Manufacturers Association. The following comments on this situation were contained in the brief of the C. Ph. M. A. :

"The charts on pages 108-110 of the green book indicate that the cost of detail men averages out to less than 15 per cent of the sales dollar. The Clarkson Gordon & Co. survey indicated 14.1 per cent for 40 companies. Using this figure as an average, you would save not more than 9 per cent of the sales dollar by eliminating the practice of detailing. The reason for this is that most detail men spend only part of their time in calling on doctors. The other part is spent in visiting

retail pharmacies and hospitals, general servicing for the company, serving as an on-the-spot point of contact for clinical investigators, and other miscellaneous duties which are essential to any national company. This was borne out by the survey conducted by Clarkson Gordon & Co., which showed that detail men spend a weighted average of 36 per cent of their time on duties other than detailing doctors."

(Association brief, p.66; Hearing, p.1960)

Mr. S. N. Conder, General Manager of the C. Ph. M. A., gave the following additional testimony:

"THE CHAIRMAN: They indicate apparently that 36% of the time of detail men on the average, weighted average, is spent on duties other than selling duties?

MR. CONDER: Yes sir, it is varied.

THE CHAIRMAN: A good deal of that would be spent in calling on pharmacists and hospitals and showing them the particular drugs?

MR. CONDER: Yes, that is correct, or in some cases actually taking obsolete stock and material, depending on how the company handles this. We have different policies."

(Hearing, pp.1962-63)

4. Expenditures on Direct Mail and Samples

As shown above in Table 13, expenditures on direct mail and samples in 1959 were respectively the second and third largest, although they were of virtually the same importance. The results of the survey for 1960, made for the Canadian Pharmaceutical Manufacturers Association, and referred to above, show somewhat different proportions, with expenditures for samples amounting to about one-third more than those for direct mail.

On the subject of direct mail, Mr. R. B. Thompson read as follows from the brief of Cyanamid of Canada Limited:

"Accusations have been levelled at the industry. . . that this form of advertising is unnecessarily expensive.

Our total direct mail expenses for literature sent to physicians in Canada in 1960 amounted to \$61,400, which, on the basis of some 17,000 physicians on our mailing list, represents a cost for direct mail per doctor of only \$3.61. . . . "

(Cyanamid brief, p.23; Hearing, p.1492)

There was much discussion before the Commission about the absolute amounts of money spent on samples by the drug manufacturers. At the hearing in Calgary, Mr. Donald Romaine, Managing Editor of The Albertan, reported to the Commission that an unnamed doctor had told him that he was receiving about \$2500 worth of samples from drug companies year in and year out. It was asserted in the brief of the Canadian Pharmaceutical Manufacturers Association that this figure was greatly exaggerated and the following figures from a survey made by the Association were given:

"A statement was made before this Commission in Calgary by a newspaperman about a doctor who receives 'about \$2,500 worth of samples from drug companies each year'. This figure is too high by at least \$2,000.

We asked our companies for the average cost per doctor of all samples distributed during the year 1960. Thirty-nine firms reported a total of \$285.17 for an average of \$7.31 per company over the 12-month period. These are all major companies in the industry, and it is doubtful that the remaining firms would produce another total of \$214.83, which means that the total cost per doctor sampled in 1960 was much less than \$500.

Nor does this mean that all doctors in Canada received \$285.17 worth of samples from these 39 companies. Many of these samples were restricted to specialists, while others were distributed only on request to a limited number of practitioners. Consequently, the average for all doctors in Canada would be considerably lower."

(Association brief, p.67; Hearing, pp.1964-65)

In answer to a question, the cost basis of samples was explained as follows by Mr. Conder, General Manager of the C.Ph.M.A.

"THE CHAIRMAN: One question occurred to us and I think it would just take a moment to clear it up. On page 67 you refer to this statement made by newspapers in Calgary about doctors receiving about \$2,500.00 worth of samples from drug

companies each year and you stated this figure is too high by about at least \$2,000.00. You go on to say that 39 firms reported a total of \$285.17 or an average of \$7.31 per company over the 12-month period.

So we will know we are both talking about the same thing, would this \$285.17 be the cost to the company, or would that represent what would be a suggested retail price?

MR. CONDER: That would be the cost to the company."

(Hearing, p.2003)

The Green Book (p.59) reproduces a quotation from an article by W. Furness Thompson, Vice-President, Research and Development Division, Smith Kline & French, reported in the Journal of the Patent Office Society (Volume XLI, Number 1, January 1959, pp.70-71) as follows:

"... It is impossible to get comparative figures of costs of promotion in recent years as compared with expenditures prior to the present wonder-drug era. However, all available evidence points to the fact that such promotion is on a scale never before known. An instance of its extent is illustrated by the statement in the FTC Report that, in introducing Aureomycin (chlortetracycline) in the United States in 1948, Cyanamid distributed ten carloads of free samples to about 142,000 physicians at an estimated cost, for the drug alone, of two million dollars (FTC Report, p.140)."

(Green Book, p.59)

In connection with this quotation, the brief of Cyanamid of Canada Limited stated:

"In this connection, however, we must call attention to an allegation repeatedly made against American Cyanamid, which has found its way into the Director's Statement (page 59) and was reiterated by Dr. Schechter before this Commission, to the effect that American Cyanamid had spent some \$2,000,000 in introducing Aureomycin by means of free samples. The original statement in the U. S. Federal Trade Commission's Economic Report on Antibiotics Manufacture (June, 1958) at page 140, reads as follows:

'When American Cyanamid introduced Aureomycin in 1948, ten carloads of samples were mailed to

about 142,000 physicians. It has been estimated that the cost of the product alone was about \$2,000,000.'

As footnote in the Report, this quotation came from a thesis by a university student who had never, to our knowledge, contacted the company about this matter. The truth of the matter was that a generous mailing of samples was made, but the cost was nowhere near \$2,000,000. Actually, the cost was \$1.25 per physician, to 142,000 physicians, for a total cost on this mailing of less than \$180,000."

(Cyanamid brief, p.21-22; Hearing, p.1490)

Mr. R. B. Thompson, of Cyanamid, gave the following additional testimony:

"THE CHAIRMAN: That is the cost of the sample itself?

MR. THOMPSON: Yes.

THE CHAIRMAN: Not the cost of mailing, and the rest?

MR. THOMPSON: No, I am sorry, that is the total cost Mr. Chairman of the package. This was a package in which was included samples, and I am quoting the total cost per physician in the mail.

THE CHAIRMAN: After paying postage?

MR. THOMPSON: After paying postage, yes. That is why I said a total cost on the mailing."

(Hearing, pp.1490-91)

"MR. MACLEOD: I was just trying to learn, if I can, your estimate of the cost of the \$1.25 for each doctor.

MR. THOMPSON: I obtained that figure from the Advertising Manager of Lederle Laboratories in Pearl River. He had been concerned about this apparent inaccuracy in the source which the Director quoted. It seemed to me that it should be set right.

It was repeated in the Director's Statement and I think it was read back in testimony before the Commission and it prompted us to investigate it, so I simply asked my colleague in the United States if it is accurate. He said no and gave me the correct figure.

MR. MACLEOD: The record will show, I think, that the retail price, the consumer's price, the list price at that time was \$21.40 for 16 capsules.

MR. THOMPSON: You mean the retail price?

MR. MACLEOD: The retail price.

MR. THOMPSON: That may well be Mr. MacLeod. You have presumably checked that. I haven't. "

(Hearing, p.1692)

On March 30, 1962, the British Columbia Court of Appeal reversed a decision of the Minister of Finance of the Province of British Columbia confirming an assessment of tax by the Commissioner under the Social Services Tax Act (B.C.) with respect to samples of drugs freely distributed in the province by Cyanamid of Canada Limited. In a letter dated December 6, 1962, Mr. Ian G. Wahn, M. P., Counsel for the company, informed the Commission that the samples in question had been distributed over a period of ten years and that their cost of manufacture was approximately \$246,240. Mr. Wahn also forwarded to the Commission a copy of a letter dated November 30, 1962, addressed to him by Cyanamid of Canada Limited and containing the following information:

" . . . The retail value could be more or less than the total value stated, and would be dependent on a number of factors. It is important to note that the majority of the samples involved represented primarily new products or recently introduced products. It is quite obvious that production costs of initial batches of new products are higher than the cost of subsequent batches. Also, special packaging, both as to design and size, is prepared for sample products, and, as this packaging is purchased in quantities which are substantially smaller than normal packaging requirements, this cost, too, is inflated. Indeed, it is impossible to set a retail value on sample items - either individually or in bulk quantities. "

5. Cost of Advertising in Journals and Cost of
Co-operative and Other Advertising
Arrangements

As shown in Table 13, 27 firms spent on the average during 1959 1.95 per cent of their net sales on advertising in journals, 0.03 per cent on co-operative advertising and 0.77 per cent on all other forms of advertising. While co-operative advertising is mentioned as a separate category, it is obvious that it is a matter of negligible importance, for, according to Table XXIV of the Green Book, only four firms engaged in it and none of them spent more than 0.72 per cent of net sales on this method of advertising. In regard to some other forms of advertising, the brief of the Canadian Pharmaceutical Manufacturers Association contained the following information:

"The green book quotes on page 111 an excerpt from Harper's Magazine referring to the 'lavish' gifts to doctors by pharmaceutical firms in the United States. To determine the extent of this practice in Canada, we polled the same 39 companies for information on their practices in this respect during 1960.

Of these 39 companies only one distributed a gift to all doctors in 1960. Eighteen firms gave no gifts whatever during the year. The remaining 20 companies reported as follows: nine limited distribution to graduating medical students and interns, 10 gave gifts on a limited basis to certain practising physicians, while one gave a pencil and map to delegates attending the British Medical Association convention in the U.K.

In all, the average cost per unit of these gifts was \$1.29. Gifts to practising physicians ranged from calendars and pocket diaries to pencil holders and ball point pens, at an average cost per unit of .82¢ each. Graduating medical students and interns were the major recipients, receiving introductory product kits, thermometers, diagnostic lights, business cards, etc., for an average per unit cost of \$2.19 for the year 1960.

It is recognized that a comparatively small percentage of firms use this type of gift in Canada, and it is obvious from the per unit costs involved that they are by no means 'lavish'. Incidentally, it is known that promotional practices of this nature are more prevalent in the United States, although it is doubtful whether the claims being made about that industry's operations are any more factual than the ones being directed against us in Canada.

The company mentioned in the green book as having provided plant tours of its U.S. company for graduating medical students is not a typical undertaking by companies in Canada. However, some of our companies do arrange plant tours of their own Canadian facilities from time to time."

(Association brief, p.68; Hearing, pp.1965-67)

6. Special Factors Increasing the Cost of Drug Advertising and Promotion

Because ethical drugs are not advertised to the patient, the pharmaceutical industry has directed its advertising primarily at the prescribing physician, for the latter decides which drug, if any, shall be used in the treatment of a patient's illness. The pharmaceutical manufacturing industry also directs part of its advertising and promotional efforts towards the retail drug trade and hospitals.

The legislation prohibiting advertising of ethical drugs to the general public, by restricting advertising and promotion primarily to the medical and pharmaceutical professions, has, it is claimed, the effect of increasing the ethical drug manufacturers' advertising and promotion costs. This was stated as follows in the brief of Cyanamid of Canada Limited:

"The structure of drug prices is profoundly influenced by the advertising methods of this industry, shaped by legislation which restricts advertising to the general public. This makes it necessary to seek means of communication other than mass media, with undeniable justification, but with accompanying increase in costs."

(Cyanamid brief, p.11; Hearing, pp.1465-66)

The costliness of the industry's advertising and promotional efforts was explained as follows in the brief of the Canadian Pharmaceutical Manufacturers Association:

"Promotion in this industry is costly in relation to lay advertising, because of the calibre of the information required and the technical nature of the data involved. Pharmaceutical literature must be carefully

prepared, screened by medical men, and presented in a manner that is quickly and clearly understood by the doctor. In addition to the advantages inherent in the product, the literature must also indicate the nature and action of the product, the administration and recommended dosage, and the contraindications, toxicity and precautions involved. By the very nature of these technicalities, the same dollars used in advertising pharmaceuticals will not bring back an equivalent ratio of readership or impact as does lay advertising."

(Association brief, p.65; Hearing, p.1956)

The subject of the relative scale of marketing costs in Canada, as compared with that in the United States, was dealt with as follows in:

(a) the brief of Cyanamid of Canada Limited:

"The smaller size of the Canadian market has the effect of increasing marketing costs. Canada has two-fifths of 1% of the world's population, is one of the largest countries of the world in area, and yet the standard of living is among the highest in the world. The cost of reaching a Canadian consumer is higher by reason of the distances between small and widely scattered population centres. In the U.S. there is a total of 14 Lederle depots, each servicing a relatively compact area. In Canada, the number of depots is only six, each servicing a sales territory considerably larger than its U.S. counterpart. . . .

Furthermore, Canada is bilingual. The industry relies heavily on promotional literature which must be distributed in both languages."

(Cyanamid brief, pp.10-11; Hearing, p.1465)

(b) the brief of the Canadian Pharmaceutical Manufacturers Association:

"By way of explanation, it is usual to differentiate between English and French language physicians when discussing advertising literature. As Canadian companies must print literature in both English and French, the cost is naturally much higher proportionately than it is in the U.S., the U.K. or France, where single languages prevail."

(Association brief, p.70; Hearing, p.1968)

7. Competition and the Cost of Advertising
and Promotion

Regarding the effect of competition on the over-all expenditures on advertising and promotion, divergent views were expressed by two representatives of the drug manufacturing industry:

(a) by Mr. K. Antoft, President of Nordic Biochemicals Limited, described by him as a small ethical drug house:

"THE CHAIRMAN: Mr. Antoft, in your brief you make a number of comments on advertising and promotion which seem to indicate that you don't just like the extent to which these things were carried on. I wonder if these comments have in your view -- this is what I want you to answer -- whether you think this is putting it too strongly, whether you feel the manufacturers have got into a kind of unfortunate rat race in having to have more and more detail men, more and more fancy advertising? Would that be putting your views too strongly?

MR. ANTIFT: I don't think that would be putting it too strongly. I deplore this. I think it has developed into a rat race. I hope our industry together with the medical association will some day, in the not too distant future, will be able to find the formula by which a serious manufacturer can get information across to the doctor without this tremendous wastage of everybody's materials and time and money. I think this is an area for the industry and for the medical profession to arrive at some solution or to get closer to a rational approach to this."

(Hearing, p.1423)

(b) by Mr. R. B. Thompson, Manager of the Medical Products Department of Cyanamid of Canada Limited:

"THE CHAIRMAN: . . . Is it your experience or is it not over the years that your company has had to step up its expenditures on literature, on intensity of detail interviewing or other matters of promotion because other companies have been doing that to a greater and greater extent?

MR. THOMPSON: Well, I have never believed that intensification by my competitor creates the need for me to increase the intensity.

THE CHAIRMAN: Unless he is taking your business away?

MR. THOMPSON: Yes, but this is not an easy thing to do if I am there first. I do think that certainly it is true these expenditures have risen, but I think the reason is rather that the new drugs that are now available are more potent, more complex, and the conservative physician - and he is rightly so - wants to have an increasingly complete story, increasing reassurance, as a drug becomes more potent before he will use it.

I would attribute any increase to the nature of the new drug rather than to the intensity of competitive activity.

THE CHAIRMAN: You don't think intensity of competitive activity has been a contributing cause?

MR. THOMPSON: No, I don't think so, no.

THE CHAIRMAN: We often think it is in some other industry, but we may be wrong in that.

MR. THOMPSON: It reaches a balance, Mr. Chairman, because if my competitor increases his effort and I increase mine to match it, it is necessary for us to raise our prices to finance it, and pretty soon somebody comes along with a price-cut, and it is terminated automatically. "

(Hearing, pp.1578-79)

8. Methods of Dealing with High-Pressure Promotion

The brief submitted on behalf of the Government of Saskatchewan by its Minister of Public Health, Hon. Walter Erb contained the following suggestions with respect to methods of dealing with high-pressure promotion:

"In our view, the advertising and promotion of drugs has gone beyond the bounds of propriety and common sense. It has been clear for some time that advertising and promotion has become one of the major costs of doing business and this has been confirmed by the material published by the Commission [Green Book, p.115]. It would seem therefore that it is important to consider methods by which this might be reduced.

It would be comparatively simple to rule that only expenditures on advertising and promotion up to a set portion of sales could be regarded as legitimate business expenses for income tax purposes. This might be deemed to be a variant of a system of price control in effect in New Zealand where only a limited allowance is made for such expenditures in the controlled final price of drugs [T. L. Hayes, 'Prescribing in New Zealand', Department of Health, New Zealand, p.7]. This at any rate would constitute one approach to the problem.

Another approach would be to set more stringent regulations regarding the type of advertising and promotion permitted.

It may also be suggested that really effective control over drug prices would probably have a greater effect in reducing unreasonably high promotion expenditures than almost any other step. In addition, steps to reduce the artificial proliferation of drugs would reduce promotional and advertising pressures."

(Government of Saskatchewan brief, pp.10-11;
Hearing, pp.767-68)

CHAPTER XII

EFFICIENCY OF ADVERTISING AND PROMOTION FROM A BUSINESS POINT OF VIEW

1. Necessity of Advertising and Promotion for the Individual Firm

Representatives of the pharmaceutical manufacturing industry made it quite clear that from the point of view of the individual manufacturer, advertising is absolutely necessary to his remaining in business. For example, the brief of Nordic Biochemicals Ltd. contained the following passage:

"When Nordic Biochemicals Limited was established in 1951, we approached our responsibilities with what appears in retrospect to be naive idealism. We assumed that all that was necessary to thrive and expand in the Canadian drug manufacturing industry was to offer the best possible product at a reasonable price, in the expectation that within a very short time we would be operating at capacity. It was thought that advertising could be held to simple announcements in one or two of the main medical journals, announcing that our products were available. No provisions for direct mail promotion, an army of detail men, or huge sampling programs were envisaged. While this philosophy was operative, the company teetered on the brink of disaster, but only with reluctance and by degrees did we accept the 'facts of life', and the company finally began to prosper. It was rapidly discovered that although doctors publicly deplore the mass of direct mail literature, a sales volume on practically any product could be created by advertising it by mail providing it is done persistently and massively. Detail men are an expensive method of securing sales, but without them, cobwebs grow on the order desk. Thirdly, in order to detail, a representative must usually 'bribe' his way into the doctor's presence by the offer of free samples in generous volume. The drug house who neglects any one of these three sales methods invites its own decline. . . .

. . .

Currently these three avenues of sales promotion

[direct mail, detail men and sampling] plus a very limited journal advertising, cost us approximately 35% of our gross sales. While we would much rather spend this money on research and development or on reducing our prices, we know from experience that without these sales expenditures, there will be no sales."

(Nordic brief, pp.14-15; Hearing, pp.1403-05)

The necessity of directing advertising to pharmacists as well as to physicians was stressed in the following excerpt from the brief submitted on behalf of Cyanamid of Canada Limited:

". . . It is equally essential that promotion of pharmaceuticals to drug store pharmacists must keep pace with that to doctors and institutions. The U. S. Federal Trade Commission Economic Report on Antibiotics Manufacture, at page 127, makes this position clear in the following passage:

'Drug-trade advertising is more important to the success of an "ethical" product than is generally realized. Although it is the physician who activates the sale, it is the druggist who actually rings the cash register. If the product which a physician prescribes is not in stock at the local drug store and the druggist cannot get it quickly from his jobber, a most unfortunate series of sales-killing events can take place. The druggist, of course, is not at liberty to change the physician's prescription. But he is free to 'phone the prescribing physician, suggesting a change to a competing product. When this happens, more harm is done than simply the loss of a single sale. Neither the physician nor the pharmacist appreciates being placed in this position, and their future attitude toward the original product can be most uncooperative. Thus, adequate drug-trade distribution must parallel the promotional campaign to physicians, and advertising to druggists plays an essential part in achieving this distribution.'

To this end, our Lederle drug representatives in Canada spend a considerable amount of time with the drug trade, in order to make sure that the pharmacists know about our products and that our products will always be available when needed."

(Cyanamid brief, pp.24-25; Hearing, pp.1496-97)

2. Advertising and Promotion as a Guarantee of Success

According to the excerpt, quoted earlier, from the brief of Nordic Biochemicals Ltd. :

" . . . a sales volume on practically any product could be created by advertising it by mail providing it is done persistently and massively . . . "

This brief was read by Mr. K. Antoft, President of the company, who also testified as follows:

"MR. MACLEOD: Do you think you could increase your sales significantly by putting more money into advertising?

MR. ANTIFT: Yes, I think if we put more money into advertising, if we had more money to put into advertising -- there is always a time lag -- that we would recover this money in probably about the same proportion. In other words, we spend 35 cents additional and we would have \$1.00 additional in sales."

(Hearing, pp.1438-39)

On the contrary, Mr. R. B. Thompson, Manager of the Medical Products Department of Cyanamid of Canada Limited, contended that large promotional expenditures alone did not guarantee the success of a drug product, if it were unacceptable for other reasons. In this respect, his evidence is as follows:

"MR. WAHN: Another aspect of this prospect of promotion is this: It has been suggested with sufficiently large expenditures it is possible to effect large sales of almost any prescription drug whether the prescription drug has any value or not. Would you say that, first of all, is this statement true, and if it is, does it happen to any extent in the industry?

MR. THOMPSON: I think Mr. Antoft of the Nordic Biochemicals made a statement to that effect, and I would like to present this package as evidence this is not true. This is a preparation called Cellothyl. This product was introduced

in Canada about 1950 as a totally safe and harmless ⁽¹⁾ and yet effective laxative, as indeed it was strongly recommended in a clinical study by Dr. Arnold Bargain, the chief of the gastro-enterological service at the Mayo Clinic, and there was every reason to suspect that this would overcome most of the drawbacks of irritant laxatives, which of course, come to be habit forming.

This product was promoted intensively for about four years with considerable expenditures behind it, and at the beginning it enjoyed a good sales volume, but later sales began to dwindle, and despite the best efforts of not one company but several companies in the United States. The Upjohn Company entered this market and put 750 salesmen to work on liquid form; the Eli Lilly Company did the same thing, so there were three people all competing for the business with the same drug.

THE CHAIRMAN: That is not a prescription drug?

MR. THOMPSON: No. This drug was promoted through physicians because it is right that physicians should manage patients with severe constipation.

THE CHAIRMAN: Is it patented?

MR. THOMPSON: No.

THE CHAIRMAN: Anybody can get it?

MR. THOMPSON: Yes. Raw material is made by the Dow Chemical Company, and it is used in food, in the food industry, and many other uses on this list. Its drug action was discovered later. There was no patent protection of any kind, but the sales began to dwindle, and now I would suspect many druggists in Canada have forgotten its name. In fact it is rather significant this bottle is half full and was never emptied because I got this from a physician's office in Ontario, and it was lying idle on the shelf for about five years, and yet this is a safe substance, which works.

I am the person who introduced this in Canada, Mr. Chairman, so I made the mistake. I believe that the reason this drug failed is because it is too difficult a burden for the physician to carry out the supervision of his patient that this kind of product requires. He would prefer to use a more active drug requiring smaller dosage and acting more promptly even though it may not be quite as safe."

(Hearing, pp.1546-47)

(1)

According to the Merck Index, some results experienced from the use of Cellothyl indicate that it is not completely safe and harmless. See The Merck Index of Chemicals and Drugs, Merck & Co.Inc., 7th Ed., 1960, p.674.

Mr. Thompson gave testimony about another laxative product, called Aerosol O.T. which he said had failed despite extensive promotion, and for the same reason (Hearing, p.1548). He then continued as follows:

"There is a boneyard which is full of products like this that seem to have merit, but where the manufacturer has either misjudged them, and there have been efforts to promote products that have marginal benefits in the belief that strong promotion would overcome the marginal nature of the benefit, but this always failed. I don't know anybody who has successfully fooled physicians over any extended period of time with a drug.

THE CHAIRMAN: I hope they wouldn't be able to fool them for too long.

MR. THOMPSON: Hexamethonium, this drug failed because it was difficult to use. Hexamethonium is very potent for hypotension, but it is a dangerous drug, and I think physicians conclude that they would rather use a less potent drug and take a little longer to get control of their patient's blood pressure rather than run risks of using a very dangerous substance, and it is out of use now.

MR. WAHN: Your point being that promotion itself is not sufficient to ensure extensive sales of drugs?

MR. THOMPSON: Very definitely.

THE CHAIRMAN: The drug must have merit or it won't continue in use?

MR. THOMPSON: Yes, indeed."

(Hearing, pp.1548-49)

3. Effectiveness of the Advertising and Promotional Methods

With respect to the effectiveness of the advertising and promotional methods, the brief of Cyanamid of Canada Limited stated:

"Drug advertising is a specialized art. We must deal with doctors, a profession notoriously and properly skeptical by training. Promotional campaigns to doctors and pharmacists

are carefully planned and executed. To the charge that such programs are wasteful, we can only answer that we as a commercial organization are averse to spending money where it is of no avail to do so. The methods used - journal advertisements, direct mail, and personal calls - are the result of experience acquired over a considerable period of time as to the most effective way of communicating what must be told. From time to time, these methods change and modify to suit the changing conditions in the industry."

(Cyanamid brief, p.22; Hearing, p.1491)

The effectiveness of the several kinds of advertising and trade promotion in conveying to doctors their first information about new drugs is dealt with as follows in the brief of the Canadian Pharmaceutical Manufacturers Association:

" . . . Of the many sources of information available to the profession, surveys indicate that the physician acquires about 95 per cent of his information on new drugs from detail men, direct mail and medical journal advertising, in that order of preference.

This is borne out in recent studies conducted by International Surveys Ltd., of Montreal which determined, among other things, where doctors first learned about specific products. As these surveys were confidential to companies subscribing to this service, the names of the products involved have been replaced by their therapeutic classifications, as follows:

DOCTORS' FIRST HEARD ABOUT PRODUCT FROM:

<u>CLASS OF PRODUCT</u>	<u>DETAIL MEN</u>	<u>DIRECT MAIL</u>	<u>JOURNAL ADS.</u>	<u>MEDICAL PAPERS</u>	<u>OTHER</u>
Antidepressant	69.8%	22.6%	--	1.9%	5.7%
Antibiotic	71.4%	14.3%	9.5%	2.4%	2.4%
Antihistamine	66.6%	16.6%	12.5%	--	4.3%
Diuretic	67.3%	20.4%	10.2%	--	2.1%

It is obvious that detail men and direct mail are the two greatest single sources of information, immediately followed by journal advertising. This is not a case of determining which media the doctor prefers, but rather the one that provides him with the earliest information, for this is the factor which determines the efficiency of any dissemination of knowledge. Many of us complain about television commercials, but we still realize that these

commercials make our favourite programs available. They are used because they perform a useful selling function. The same applies to pharmaceutical information and advertising. Many complain about direct mail, for example, yet it serves a basic need for product information and as indicated is used by the profession for this purpose."

(Association brief, pp. 57-58; Hearing, pp. 1924, 1933-34)

The Green Book, (para. 194, p. 118), quoted a portion of an article which appeared in Newsweek to the effect that promotional methods had gotten out of hand and that the present large expenditures must be checked. The excerpt contained an admission to this effect by John T. Connor, President of Merck & Co. Mr. R. B. Thompson, Manager, Medical Products Department, Cyanamid of Canada Limited, commented on this as follows:

"MR. THOMPSON: If Mr. Connor meant by that, that he would like to see the cost of marketing reduced or a greater efficiency introduced, then I would agree with him. I would like to see that happen, too. But I don't for one minute think that the cost of marketing has gotten out of hand, and certainly I don't think it is true in my own company.

If I could find a way to get an extra 10% of efficiency out of the promotional dollars my company spends I would be delighted, and I would go to great pains to do so if I thought I knew how to do it.

. . .

MR. HUME: You don't agree with the statement in the Green Book that the present large expenditures are not justified? You consider they are justified?

MR. THOMPSON: I don't know of any way to reduce them, Mr. Hume. I just wish I did. I don't think it is out of hand. I think that the levels of promotional expense are the result of many years, 80 years of experiments. During that period almost every conceivable combination of promotional methods has been used in an effort to seek a more effective way. I think that the methods that are being used now are the best that have ever been devised, and most efficient, and I don't think they are out of hand."

(Hearing, pp. 1576-78)

4. Effectiveness of Direct Mail Advertising

The data given in section 1 of Chapter XI on the relative expenditures by drug manufacturers on different forms of advertising and promotion indicated that direct mail advertising was used in varying degrees by different companies. The brief submitted on behalf of the Canadian Pharmaceutical Manufacturers Association made the following comments on the differing views among drug manufacturers as to the effectiveness of direct mail advertising and gave some particulars of the use of this form of advertising:

" . . . Some companies do no direct mail advertising whatever on the grounds that detail men are the best means of providing complete information to the doctor, and the fact that a large percentage of direct mail is discarded.

Other companies believe that direct mail is an efficient yet economical method of advising the doctor of the product. These firms point out that while a good percentage of direct mail may be discarded it is still the least expensive means of communication, costing as it does but a few cents per doctor. This variance in the use of direct mail was shown in a survey of mailings by 33 companies over an eight-month period from January 1, 1960 to August 31, 1960:

<u>Total No. of Mailings over 8 Months</u>	<u>No. of Companies in each Category</u>
0 to 4 mailings	7 firms
7 to 12 mailings	7 firms
15 to 26 mailings	6 firms
34 to 48 mailings	9 firms
83 to 131 mailings	4 firms

While the average per company was 27 pieces for the eight-month period, the average is not a sound figure in this case. It will be noticed that four firms sent out considerably more direct mail pieces during this period than all the other 29 companies combined. Yet it is conceivable that the advertising costs of these four firms may have been lower than the others in view of the minimal cost of direct mail itself.

Furthermore, this does not mean that each of these mailings went to every doctor in Canada during

the eight-month period. Many of them were limited to specialists, such as anaesthetists or urologists. For example, a company may have two new products: a pediatric substance and a psychopharmacological preparation. Information on both products would not normally be sent to both pediatricians and psychiatrists.

In addition, not all direct mail is product advertising. A good percentage is non-promotional in nature and we wish to leave with the Commission a sampling of this type of literature for later study [Exhibit T-7]".

(Association brief, pp.59-60; Hearing, pp.1935-37)

The views of drug manufacturers as to response which doctors give to direct mail promotion were outlined to the Commission by:

(a) Mr. R. B. Thompson, Manager of the Medical Products Department of Cyanamid of Canada, who read from his company's brief and testified as follows:

" ' . . . It has been claimed that the bulk of direct-mail advertising goes unread, and even unseen, by the majority of doctors. This is simply not so. Our representatives, when they call on doctors all over Canada, are repeatedly assured that direct mailings are in fact read by the doctors, are welcomed by them, and are considered by them to be informative and useful. Some doctors, notably medical school professors, have testified that they are inundated with an avalanche of excessive and uninformative advertising which they believe is both wasteful and too commercial, but this view is definitely not shared by most practicing doctors.'

THE CHAIRMAN: That statement is on reports from your representatives?

MR. THOMPSON: Yes.

THE CHAIRMAN: Based on their reports?

MR. THOMPSON: Yes. We have had a number of occasions when representatives would walk into a physician's office, mention a product, and the doctor would say why I got that in the mail a few days ago. The physician would know

of the product which he would otherwise not have heard about.

THE CHAIRMAN: That is good timing, of course.

MR. THOMPSON: We don't always do it that well Mr. Chairman. That is one of the purposes of direct mail; is to rouse the physician's interest so that the salesman, when he visits him, can make more efficient use of his time."

(Cyanamid brief, p.23; Hearing, pp.1492-93)

"MR. FRAWLEY: Now there have been doctors here, reputable doctors before this Commission who indicated - and there is an account of it and if anybody wants to spend the time reading the Kefauver Report - that this is an enormous waste.

MR. THOMPSON: I suggest those comments are made by gentlemen who have never been in the pharmaceutical business. There are many experts all of a sudden who have never had experience in this business.

MR. FRAWLEY: How about the doctor that takes 100% of your receipts from Lederle and puts 90% in his wastebasket? If there are those kind of people you would have to admit it was wasted effort.

MR. THOMPSON: I most certainly would not admit that. What do you suggest happens to medical journals after they have been read? What I am interested in is what happens to advertising material between the time it reaches the physician's office and the time it goes in the wastebasket. It must inevitably end up some place but I am interested in what happens to it when it is in that physician's office and you may be interested in a little evidence in that regard.

This is just one example of a direct mail campaign, single mailing in fact and this is reported in the Medical Mailer, which is a newsletter from Canadian Mailings Limited dated June 1961 and I would like to quote:

'A major Montreal Pharmaceutical house. . .'
and this incidentally was not our company -

' . . . recently mailed to 10,959 general practitioners and pediatricians. The mailing consisted of a postage-saver, postal permit envelope containing a simple one-page letter accompanied by an unstamped return card (request for a sample of a pediatric product).

The return card required the doctor to write out his name and address, sign and put his own postage stamp on it. To date, this mailing to 10,959 doctors has brought 2,943 completed, stamped returns'.

THE CHAIRMAN: What was the date that was sent out?

MR. THOMPSON: June. This bulletin Mr. Chairman is dated June 1961. It says recently in regard to the timing of the mailing.

MR. FRAWLEY: What were they advertising?

MR. THOMPSON: I will have to read what they say. It was a request for a sample of a pediatric product. We don't know the nature of the product.

MR. FRAWLEY: They don't report the ---

MR. THOMPSON: But I have personally signed letters to physicians in Canada and I will give you - quote you an example, similar example of a letter suggesting the use of a preparation containing a narcotic and inviting the physician to return a reply card to obtain a small sample, very modest sample of this narcotic preparation and the sample would then be sent to him.

As you probably are aware, Mr. Frawley, before we are permitted to despatch a sample containing a narcotic under Federal law we are required to have on file a signature in ink made by the physician personally indicating his desire to have this shipment made.

The mailing that I am thinking of brought back a return of more than 27% of these cards and therefore we know that this percentage of the mailing reached the personal attention of the physician who signed it and whose signature has to be verified so I suggest to you Mr. Frawley this is useful, as many physicians believe but the physicians who have testified before this Commission apparently do not."

(Hearing, pp.1661-63)

(b) Mr. S. N. Conder, General Manager of the Canadian Pharmaceutical Manufacturers Association:

"MR. CONDER: We find, for example, we have many instances where a company introducing a new product will initially introduce this product through various advertising

means and probably one of the first to arrive on the doctor's desk will be a direct mail piece. As a result of these direct mailings they get back a considerable number of requests for further information on the product which could have come only from this particular mailing.

Quite often the mailing literature will include a little reply card. The little reply card will state 'Please send me a sample of this product and complete product information'. This card is then placed in the mail by the doctor. When the company receives it they send the information, plus a sample of the product so that he may study that sample in practice.

THE CHAIRMAN: I suppose the position, as far as you are able to state it, would be this growing volume of direct mail advertising results in many doctors not reading it. Nevertheless, there is enough of it read it is worthwhile to continue to send out direct mail?

MR. CONDER: Yes sir, I think it is a principle of advertising in general that regardless of what form of advertising it may be, professional or lay, there is a considerable portion of the readers or people who receive this particular form of advertising who pay little or no attention to it, some dislike it, others like it and others are neither here nor there. As long as that advertising does produce a certain percentage of results then it is worth the time of the company concerned."

(Hearing, pp.1953-55)

5. Evidence of Some Pharmacists as to the Effectiveness of the Pharmaceutical Manufacturing Companies' Promotional Campaigns

During their appearances before the Commission some representatives of associations of pharmacists were asked whether from their experiences they could express any opinions as to the effectiveness of drug manufacturers' promotional campaigns in leading to a substantial increase in the number of prescriptions for the drug being promoted. It was made clear by these representatives that while druggists are informed by detail men that a particular drug is being promoted, they are not informed as to the scale of the promotion or its nature in relation to the medical profession. None of the pharmacists, therefore, was in a position to judge how effective any particular promotion had been.

Mr. J. W. Richardson, Vice-President, The Manitoba Pharmaceutical Association, thought that a large campaign by a drug manufacturer to promote a particular product would often result in an increased sale for a period at least but the nature of the product would have a bearing on the result (Hearing, pp.690-92). The following evidence by Mr. Douglas White, Member of the Council of The Saskatchewan Pharmaceutical Association, is to much the same effect:

"MR. WHITE: All I would say, yes, it depends sometimes on the type of promotion, whether it be direct contact by a detail man or literature. There is quite an effect by each one of those on prescriptions, but we definitely do find that things are prescribed after having been --

MR. MACLEOD: Perhaps you would amplify on the point you mentioned that you found a difference in promotion by detail men and direct mail?

MR. WHITE: We cannot tell what literature they get, because we don't necessarily get the same literature as the medical man does. You cannot tell how much literature they get, but we do know when the medical representatives are in town or in our building, and certainly that is their job and they do increase the use of their prescription products.

MR. MACLEOD: That is after detail men come around for a particular company and pushing a particular product you will find increased sales of that product?

MR. WHITE: It depends what the product is of course, because the medical man may not have occasion to use it. You may not have a call for it for weeks."

(Hearing, p.836)

Mr. Douglas Denholm, Registrar of The Pharmaceutical Association of the Province of British Columbia, said that in his experience some promotional campaigns of drug manufacturers appeared to have a marked effect on the number of prescriptions for a particular product while other campaigns had little or no effect. His evidence included the following:

"MR. DENHOLM: . . . Certainly when a new drug comes on the market the pharmacist is usually advised by the company's representative. He is also advised that physicians have been detailed on it or they have received information on it and certainly

in some cases this promotion appears to be effective and this effect is noted in an increase or an immediate rush of prescriptions for this particular item. In other cases there is no effect, which would indicate little or no effect - which would indicate the promotion wasn't successful. You ask me to relate this development in the pharmacy to the actual promotion that was done. I can't do that because I am not familiar with the actual promotion done, only it was being done."

(Hearing, pp.1289-90)

CHAPTER XIII

ALTERNATIVE METHODS OF DISSEMINATING INFORMATION ON NEW DRUGS

1. Refresher Courses on New Drugs as an Alternative Source of Information

Refresher courses may help the professional man to keep up with developments in the drug field. Various efforts in this direction are made by professional groups. Mr. Douglas Denholm, Registrar of The Pharmaceutical Association of the Province of British Columbia, mentioned in his evidence a refresher course of one night a week for fifteen weeks sponsored by the Faculty of Pharmacy of the University of British Columbia and the Education Committee of the Association. He also referred to a two-day refresher course under the same auspices and to arrangements made for a panel of speakers to tour the province and speak to pharmacists on new drugs and developments in pharmaceutical practices (Hearing, pp.1276-79).

With respect to post-graduate medical training, the Final Report of the Hinchliffe Committee to the British Ministry of Health contains inter alia the following conclusions and recommendations:

"(xii) There is a clamant need for systematic postgraduate instruction of general practitioners in pharmacology and therapeutics; the average practitioner is unable to judge the validity of the makers' claims for the many new drugs now produced.

. . .

(xiv) Wider use should be made of refresher courses for general practitioners. . .

(xv) Deans and Directors should be asked, where appropriate, to consider including in the syllabus for refresher courses instruction about advances in practical therapeutics and the merits and demerits of new drugs and some indication of costs.

. . .

(xviii) The organisation of postgraduate seminars and lectures for general practitioners should be encouraged." (1)

2. Articles in Journals Intended for Doctors

Evidence has been presented to the Commission on the abundance and quality of articles appearing in the medical and trade journals. This evidence is relevant to questions concerning the value of drug manufacturers' expenditures on advertising and promotion in disseminating knowledge of new drugs because, to the extent that the articles are written by investigators wholly independent of the drug companies, they constitute an alternate source of information. The evidence shows, however, that some of the research articles, including some in medical association journals, have arisen from research projects sponsored by drug manufacturers. To the extent that this is true, the medical journal literature is not an independent, alternative source of information, but derives from the expenditures of drug companies themselves. The following evidence of Dr. Mark Nickerson, Professor and Head of the Department of Pharmacology and Therapeutics at the University of Manitoba, relates to this situation:

"There is an additional factor which Dr. Gemmell alluded to and that is the fact that you very frequently are at a loss to get a full evaluation of the drug even after a number of papers have been published.

First of all most of the initial publications in the medical journals are publications by investigators specifically selected by the drug house and subsidized by them to a greater or lesser extent.

This is necessarily so because the studies were at least started and often entirely completed before the drug was available to the medical profession in general. It is perhaps - I am speaking from hearsay now - it is fairly general knowledge, which I think perhaps the members of the Department have been able to

(1)

Great Britain, Ministry of Health, Final Report of the Committee on Cost of Prescribing, Her Majesty's Stationery Office, London, 1959, pp.6-7.

verify in various instances, that drug houses have a sort of hierarchy of investigators to whom they initially give the drug.

That is, when a drug house comes out with a new drug, which is really an advance, you will find that the initial investigators who receive it are among the very best investigators on the Continent.

When a drug comes out which is either what we refer to as 'a me too drug' or of questionable merits, that the initial publications are usually by people about whom you have never heard before; so that they select the investigator.

Now, particularly in the second category, although they are publications, these are usually quite meaningless. They do not have the proper control and it is very difficult to evaluate them.

I think the classic example of this is a survey that the Department made before preparing our lectures on the subject of tranquilizers two years ago.

This was the question of the use of what we refer to as minor tranquilizers; things like meprobamate, in the treatment of anxieties in patients who are just mildly disturbed. This is not psychotic.

In a survey of something like 200 papers - there is plenty of literature in this field now - there was no new single paper which convincingly demonstrated that this tranquilizer would do more than one of the old-fashioned sedatives like phenobarbital for this type of patient. So that in his practice a doctor would not possibly be able to go through 200 papers on the subject. I think he is pretty much dependent on what is said in the promotional literature."

(Hearing, pp.540-41)

"THE CHAIRMAN: It has been suggested, Doctor, that only those tests showing what might be called the spectacular or excellent results are likely to be published. If the results are mediocre the test may be forgotten about and the results never published.

DR. NICKERSON: This is, I think true for two reasons.

One is that the initial studies are largely supported by the pharmaceutical houses.

If a man starts out with a few bad results and is obviously not enthusiastic about the drug, they are not going to push for a completion of the series.

Sometimes you have to push the investigator to get the results all completed and published.

I think another reason rests on the physician. It is actually a lot of work to do a proper clinical trial and to write it up.

If the physician is getting some results which appear to him to be better than he might obtain from another preparation, he is going to be very interested in continuing this.

If he is getting poor results he is going to be anxious to get those patients out of the trial and back to some other medication he feels is beneficial to them, as quickly as possible, so that I am sure that this occurs."

(Hearing, pp.543-44)

The paucity of medical journals published in Canada was stressed in the evidence of Dr. Nathan Schechter, of Ottawa, who said that most of the leading journals relied on by the medical profession came from sources outside Canada:

"MR. MACLEOD: You spoke of receiving information from the medical journals too?

DR. SCHECTER: Yes.

MR. MACLEOD: Are a number of these medical journals published in the United States and in England?

DR. SCHECTER: Yes.

MR. MACLEOD: Is it the situation, then, that the Canadian market will not support a wide variety of medical journals?

DR. SCHECTER: We have very few in Canada.

MR. MACLEOD: The principal one being the Canadian Medical Associates?

DR. SCHECTER: Yes.

MR. MACLEOD: And apart from that the leading journals would come from sources outside of Canada?

DR. SCHECTER: That is right."

(Hearing, pp.251-52)

Dr. J. P. Gemmell, Associate Professor of Medicine at the University of Manitoba, mentioned a number of medical journals, namely, "The Manitoba Medical Review", "The Canadian Medical Journal", "The Journal of the American Medical Association", "The New England Journal of Medicine", and "The American Journal of Medicine". In his opinion, all contained in their articles a great deal of information useful to the medical profession (Hearing, pp.496-98). In addition to the publications mentioned above most of which are published by medical societies, there are certain periodicals which were termed "trade journals" by Dr. J. P. Gemmell. These journals are not "trade journals" in the usual sense but are journals devoted to medical subjects, sometimes of a specialized character, which are issued by a publicity house or industrial company. The space devoted to advertising usually forms a minor part of the publication and Dr. Gemmell described the advertisements as "prestige advertising". In his opinion, some of the articles in such publications are quite well done (Hearing, pp.501-02).

There may be a considerable time lag between the date of the introduction of a new drug and the appearance of any substantial volume of medical journal literature relating to it. In the interval members of the medical profession are largely dependent for information on the material issued by the manufacturer of the new drug. This was the general view taken by physicians appearing before the Commission, although Dr. J. P. Gemmell of the University of Manitoba thought that the information would have appeared in medical journals before it is available in promotional literature if the doctor had the time to search the medical journals to find it (Hearing, pp.523-24). However, his colleague, Dr. Mark Nickerson, said that such prior publications often consist of personal communications or papers presented at some conference which frequently is sponsored by the drug manufacturers (Hearing, pp.539-40). According to Dr. Nickerson, it takes from six months to nine or ten months to have an article published in a journal like the American Journal of Medicine (Hearing, pp.542-43).

With regard to the time lag between the appearance of a drug and the publication of articles on it in medical journals, Mr. S. N. Conder, General Manager, C. Ph. M.A., testified that a medical association journal is naturally limited as to the amount of space it can give to a particular drug and that because a medical journal invariably has a great backlog of information to publish, the editor has to exercise judgment as to what is pertinent at the time with regard to a particular issue (Hearing, pp.1928,1930). In his opinion, the extent to which doctors rely on medical papers for information on new drugs would depend on a number of factors, such as whether the doctor concerned was a general practitioner or one who was more of a university professor than a practitioner (Hearing, p.1930). The latter point was emphasized by Dr. R. W. Shepherd, Medical Director, Ciba Company Limited, who testified as follows:

" . . . as Mr. Conder was just saying, I think he was touching on a point which is very pertinent. That is, that the specialist in a large university centre may acquire a lot more information from scientific papers and medical meetings than his colleagues in the smaller centres, and particularly in the rural areas where they rely almost exclusively upon the material supplied to them through the industry.

I think this factor has to be taken very seriously into consideration, Mr. Chairman. Again I say it is difficult to be sure exactly where the doctor gains his total information about drugs. Certainly, the first information does reach him from the industry, because, as you pointed out, it has not yet reached the medical press. Thereinafter he gains further information from medical readings and papers and colleagues and discussions, and so on, but if he wishes he has made available to him by the industry the most complete information which is available on that drug.

The industry makes a special point of gathering together all the papers and reports on any product that it is interested in, and it is very ready to make this available to any physician who wishes it."

(Hearing, pp.1931-32)

3. Articles in Journals Intended for Druggists

According to Mr. Walter Maday, President of The Alberta Pharmaceutical Association, the sources of information on drugs expected to be found in an ordinary drug store are, in addition to the official compendia : New and Nonofficial Drugs, published by the Council on Drugs of the American Medical Association; The Drug Index, published by Drug Merchandising; and the Compendium of Pharmaceutical Specialties, edited by Dean F. N. Hughes of the Faculty of Pharmacy, University of Toronto. As some time is required before information on new drugs finds its way into official pharmacopoeias and reference books, pharmacists have to rely in the meantime on trade journals such as Drug Merchandising and Canadian Pharmaceutical Journal and on information supplied to them by the drug manufacturers (Hearing, pp.1092-95). It should be noted however that Mr. Douglas Denholm, Registrar of The Pharmaceutical Association of the Province of British Columbia, testified that the information in journals and publications to which many pharmacists subscribe is later coming out than the initial information despatched by the manufacturers. Therefore, according to Mr. Denholm, there is a brief period, when the only information available to the pharmacist is that given to him by the manufacturer (Hearing, pp.1273-74).

Some of the evidence given by the representatives of associations of pharmacists who appeared before the Commission related to the contents of trade and professional journals which are generally read by druggists in Canada. The two principal journals referred to in such evidence were Drug Merchandising, a monthly periodical published by Maclean-Hunter Publishing Company Limited and the Canadian Pharmaceutical Journal, the official publication of the Canadian Pharmaceutical Association.

From the evidence and the copies of Drug Merchandising shown to the Commission, it is apparent that this trade journal is devoted, as its name suggests, to the merchandising aspects of the operation of a drug store. The emphasis in the publication thus tends to be on ways to make the operation of a drug store profitable and the editors devote space to the various lines of merchandise sold by a modern drug store, such as cosmetics, gifts, etc. At the same time the publication carries information relating to prescription drugs. For example, in the issue of August 1960 there were two sections dealing with "New Prescription Specialties" and "Drugs to Watch". The first contained descriptions of eight drugs or drug preparations and included the brand name, the generic name, manufacturer's name, composition, indications, doses, available dosage form and, in some instances, contra-indications. The other section gave brief reports on investigations of the uses of certain drugs.

In the submissions made to the Commission on behalf of the Canadian Pharmaceutical Association, considerable emphasis was laid on what might be termed the professional or scientific content of the Association's Journal, although it was evident that considerable attention was also devoted to what were termed the commercial aspects of retail pharmacy. It appears to the Commission that in view of the multiplicity of merchandising lines which the drug store now carries the retail druggist must increasingly concern himself with marketing matters while at the same time seeking to maintain his professional career. It is not surprising, therefore, that the Association Journal tends to reflect these sometimes divergent interests but the Commission was assured that professional considerations remain to the fore in the editorial direction of the Canadian Pharmaceutical Journal.

The following contents appear in the March 1961 issue of the Canadian Pharmaceutical Journal which was filed with the Commission (Exhibit T-4). On page 2 appears a listing of the official names, commercial availability and uses of fourteen drugs. Pages 10-12 and 45-49 seem to consist of serious medical or scientific literature. Finally, on pages 36, 38, 40 and 42 there is a section entitled "New Pharmaceuticals" by Dean F. N. Hughes of the Faculty of Pharmacy, University of Toronto. This section consists of write-ups of some 51 drugs or drug preparations. They include the following information: brand name, generic name, chemical name, ingredients in mixtures and exact amounts thereof, indications, administration, available dosage forms, and the name of the manufacturer. There is no information on price.

An analysis of the contents of eleven issues of the Canadian Pharmaceutical Journal in 1960 and 1961 and of the readership of the Journal was given in the brief of the Canadian Pharmaceutical Association. The following portions are quoted:

"... It is sheer misrepresentation to state that the Canadian Pharmaceutical Journal shows any preoccupation with purely commercial activities. The Director has, in his possession; many, if not all, of the issues of The Journal of the past several years and the Commission has probably had an opportunity of judging these matters for itself.

In June, 1961, with a change of editorship in the office, the Association conducted an intra-office study of The Journal --- its production, format editorial make-up and advertising content. The eleven issues of June 1960 to May, 1961 (September, 1960 presented here as a most worthy Exhibit, was omitted due to its exceptionally heavy editorial content) contained a total of 322.6 editorial pages, 20% of which was in the French language, classed as follows:

Category	Description of Category	Total Pages Editorial	% of Editorial Content	% of Total Magazine Pages
Associa- tions	C.Ph.A.; Prov. Assoc.; C.Ph.A. affiliates; C.P.M.A.: P.A.C.. Internat.	50.1	15.5	8.7
General	P-R; History, Industrial; Letters; Poison Control; Publi- city	42.4	13.1	7.4
News	News of Pharmacy, Pharmacists and Manufacturers	35.2	11.0	6.1
Practical Pharmacy	Items concerning Pharmacy or finan- cial operations or products	64.0	19.8	11.1
Professio- nal Phar- macy	Items related to the pharmacist and knowledge of drugs and health	73.5	22.8	12.8
Scientific	Items requiring advanced know- ledge-largely the Scientific Section	35.4	11.0	6.2
Magazine Layout	Cover and title page only	22.0	6.8	3.8
TOTALS		322.6	100.0%	56.1%

Total Magazine Pages for Eleven Issues (including covers) - 576

Total Editorial Content of Eleven Issues - 322.6
pages

A readership survey of the Canadian Pharmaceutical Journal, conducted by mail in late 1957, was responded to by readers from a geographical, employment, and rural-urban cross-section in the same percentage ratio as our total subscription list. It told us:

Do you read The Journal regularly, occasionally or only sometimes?

90% regularly
9% occasionally
1% only sometimes

Do you read only the editorial material, only the advertising, or both?

12% only the editorial
2% only the advertising (These were all company
representatives.)
86% read both advertising and editorial

Do you read The Journal from 'cover to cover', the majority, or less than one-half?

19% from cover to cover
68% the majority
13% read less than half

Check the features which you read regularly .

80% read the editorial
62% read the Secretary's Desk
40% read From the Past
74% read the news items
70% read the Manufacturers Notes
87% read the New Products
65% read Pharmacy Administration
55% read Seminar
58% read Production and Marketing
56% read the Scientific Section

Additional:

57% stated they kept copies and referred back to them for at least one year

An additional 14% filed certain sections for later reference

Each copy is read by 1.69 persons. Since every registered pharmacist receives his or her own copy, the additional readership is in the cosmetic and unregistered clerk class. While not pharmacists, these people do recommend certain purchasing to owners."

(Association brief, pp.103b-03e;
Hearing, pp.2584-92)

4. Proposals for Government Sponsorship of a
Publication Giving Objective Valuation of
New Drugs

In their submissions to the Commission, many institutions and organizations including the Consumers Association of Canada (Hearing, p.59), the Canadian Federation of Agriculture (Hearing, p.174), the Maritime Federation of Agriculture (Hearing, p.414), the Government of Alberta (Hearing, p.867) and the British Columbia Branch of the Consumers Association of Canada (Hearing, p.1160) stressed the need for a publication which would make an objective and critical appraisal of new drugs. In most cases the view was expressed that such a service should be instituted at the expense of the government with the co-operation of the Food and Drug Directorate and the medical profession. With respect to this matter, the brief of Cyanamid of Canada Limited contained the following comments:

" . . . In this regard, we would be in favour of an official bulletin or other regular publication designed to acquaint doctors and hospitals and drug purchasing agencies with information on the latest developments in the drug industry. We feel that such a publication is, in fact, long overdue and we would be prepared to give active support to its publication.

We have made some preliminary investigations along this line and we have received encouraging expressions of support from members of the medical profession and the industry itself. We feel that in order to be sufficiently authoritative, the publication would have to bear the stamp of approval of the medical profession, preferably of the Canadian Medical Association, as well as the government. In this regard the Food and Drug Directorate has already facilities at its disposal to enable it to contribute substantially to the formation of an organization to publish this type of review. We feel that

the major ethical manufacturers would be more than happy to submit materials and results of clinical investigations to the publication.

Should this step prove successful, this co-operative organization could possibly extend its activities to a wider field including the review of product claims, the establishment of improved standards of purity and quality, reports on clinical tests and other matters of interest to the industry."

(Cyanamid brief, pp.48-49; Hearing, pp.1537-38)

In view of these proposals, it is of interest to examine the situation in other countries. In the United States, there is a private publication called "The Medical Letter", which carries no advertising and is intended to provide doctors with the information on new drugs. The following comments of Dr. Mark Nickerson of the University of Manitoba probably reflect the general view of practitioners of the value of this publication to the medical profession:

"DR. NICKERSON: . . . The Medical Letter is an attempt by a group of people to do this type of evaluation for the physician. As was brought up earlier, they are not infallible, but in our experience they are infinitely more reliable than any other type of greatly condensed information. This is exemplified I think by the fact our Department felt this was sufficiently important so that we obtained a subscription to the Medical Letter for all graduates of this year's class, and I think it will do them a lot of good."

(Hearing, pp.546-47)

In Great Britain, the Final Report of the Hinchliffe Committee contained the following conclusions and recommendations:

"159. The evidence we have suggests that general practitioners would welcome advice and information to enable them to put the manufacturers' claims in perspective. So great is the volume of advertising material despatched from the manufacturers that much of it goes unread. The amount of time available to practising doctors for reading is limited. Whatever information is necessary to enable them to prescribe efficiently should come to them therefore in a form which can be readily assimilated.

160. We regard the provision of adequate information, together with the improvements in training and education which we have recommended in the preceding section of our report, as the key to good prescribing. Indeed this appears to us to be the only alternative to some form of restriction for ensuring economy as well as efficiency in prescribing. What the general practitioner needs above all in this context is

- (i) a critical and unbiased statement of the advantages of new drugs compared with existing products; and
- (ii) information on the cost of treatment compared with that using existing products whether proprietary or standard.

This latter information is not difficult to obtain and our interim report indicated our views on how it should be provided, e.g. through the medium of a comprehensive prescribing handbook. Whatever form the new handbook takes, it is clear to us that something more is needed to provide the information at (i) above. This information is usually difficult to obtain especially in the early stages of a product's existence.

161. We have given careful thought to the suggestions outlined in paragraphs 156-158 above, namely the establishment of a special independent information centre; the dissemination of information through Prescribers' Notes or another publication; and the production of a card index of new drugs. It is clear that whatever form it takes, the information must be authoritative and must reach prescribers quickly as new products become available. The organisation which undertakes the task of informing practitioners on new products must, therefore, have facilities for obtaining authoritative opinions and for editing, publishing and distributing the results. As the information is intended for general practitioners, it would be advisable if the service were in the hands of those who understand their needs.

162. In our interim report we made various suggestions with regard to the expansion and wider circulation of Prescribers' Notes. Since taking further evidence it has become clear to us that many doctors tend to regard the Notes as not presenting a sufficiently independent point of view. For this and other reasons we have come to the conclusion that Prescribers' Notes, in spite of its undoubted usefulness, is not an adequate or suitable channel for conveying to

doctors information of the sort we think they really need.

Nor do we regard a card index, with the extra clerical work it would entail, as a practical source of reference for the busy doctor.

163. We recommend the establishment of an independent publication to distribute up-to-date information to general practitioners and other doctors in the National Health Service. The Journal, which would replace Prescribers' Notes and which might be called 'Prescribers' Journal', would be run by a small Council including physicians, general practitioners, pharmacists, a pharmacologist and a statistician. The Council might be appointed by the appropriate professional bodies. It would determine matters of policy and its members would be expected to contribute their views on important topics. It would appoint a whole-time editor and would seek advice from outside experts whenever necessary.

The Journal should be independent of the pharmaceutical industry and of the Ministry of Health. It would be a journal run by the medical profession for the profession and should be circulated to all doctors in the Health Service and senior students.

Details about the scope of the journal and mechanics of production could be decided by agreement between the professional bodies concerned but we would suggest that the general aim should be to produce it at regular intervals (monthly or quarterly) and that it should include information about new drugs and preparations, the results of clinical trials, editorial comment and perhaps correspondence. We suggest that the journal should be published and distributed by the Ministry of Health who might also be asked to pay for the editorial organisation.

We accordingly recommend that the Minister should approach the appropriate professional bodies who would be asked to take responsibility for producing such a journal for the medical profession." (1)

(1)

Ibid, pp.50-52.

Although a new journal was established in Great Britain to implement the above recommendation, it is not independent from the Ministry of Health, as appears from the following article reproduced from the July 1961 issue of the Canadian Medical Association Journal:

" 'PRESCRIBERS' JOURNAL'

VIRTUALLY since the beginning of the National Health Service in Great Britain the amount paid out on drugs has caused great agitation in many circles, and to the end of economical prescribing there exists a considerable official team to give the doctor advice and criticism.¹ In addition, the Ministry of Health has, for some years, been publishing a circular entitled Prescribers' Notes which offers detailed guidance on the costs of drugs in current use. Despite this, the final report² (1959) of the Hinchliffe Committee on Costs of Prescribing recommended that a new journal should be established 'to distribute to general practitioners up-to-date information about new drugs and preparations and the results of clinical trials.'

The first issue of such a journal, called the Prescribers' Journal, appeared in early April. It is issued free, every two months, by the Ministry of Health and the Department of Health for Scotland to all doctors in the Health Service and to medical students in their clinical years.

Though the journal was to be run 'by the medical profession for the profession' and 'independent of the pharmaceutical industry and of the Ministry of Health',² the Ministry of Health decided 'it has not proved practicable to arrange for the journal to be produced in the way suggested by the Hinchliffe Committee'.³

The journal sets out 'to provide the doctor with early and reliable information about new pharmaceutical products'. As an editorial¹ in the British Medical Journal comments dryly, 'This is a tall order - even for a periodical launched under Government auspices at public expense. . . .'

The Hinchliffe Committee had felt that the profession could not reasonably rely on the manufacturers both to produce new drugs and to describe them in an entirely disinterested way and that the average doctor was unable to judge the validity of the claims made by the manufacturers' representatives. The journal was conceived to fill the need for independent

guidance and to be based neither on the wish to sell a drug nor on the wish to reduce expenditures

Whether such a journal can be 'independent' in this sense is questionable; but, more to the point, whether the medical aim of good prescribing - rather than the political aim of economical prescribing - is achievable in this fashion is even more questionable. What really makes for good prescribing, as one enlightened writer ⁴ has said, 'is sound undergraduate education in therapeutics and continued postgraduate reading and courses throughout a doctor's working life.'

REFERENCES

1. Annotation : Brit. M.J., 1:1021, 1961.
2. Great Britain, Ministry of Health : Final report of the Committee on Cost of Prescribing in England and Wales, Her Majesty's Stationery Office, London, 1959.
3. Great Britain, Ministry of Health: E.C.L. 25/61.
4. Leading Article : Brit. M.J., 1:1285, 1959." (1)

In the same issue of the Canadian Medical Association Journal, "The London Letter" by Mr. S. S. B. Gilder contains the following comments on the first number of Prescribers' Journal:

"Effective Prescribing

The exhortations to the general practitioner to standardize, rationalize and economize in prescribing for his Health Service patients continue. Two new publications in England deal with this problem; one will help the G.P. and the other will probably confuse him. The one which may prove helpful is the new Prescribers' Journal, which has appeared as a free issue to all general practitioners from the Ministry of Health and is intended to give up-to-date information about new drugs and preparations and the results of clinical trials. Those responsible are a very respectable collection of pharmacologists and clinicians, and the first number contains discussions of griseofulvin, topical corticosteroids and penicillins. The periodical will appear every two months and is of course paid for with public money. One wonders what sources of secret

(1)

"Prescribers' Journal", Canadian Medical Association Journal, Vol.85, July 1, 1961, p.40.

information on new products its sponsors will have that the editors of the independent medical journals have not already had, or whether the general practitioner will be more encouraged to read the new journal when he has already been presented in the older periodicals with articles, editorials and abstracts on griseofulvin and the other products discussed in the first number. One can only wait and see, but the problem is inescapable - either one publishes inaccurate or even misleading information on a new product quickly or one waits for a longer-term assessment and publishes late. No government or any other power can alter this perpetual dilemma of the medical editor." (1)

(1)

S. S. B. Gilder, "The London Letter", Canadian Medical Association Journal, Vol.85, July 1, 1961, p.43.

CHAPTER XIV

SOCIAL VALUE OF ADVERTISING AND PROMOTIONAL EXPENDITURES BY DRUG MANUFACTURERS

1. Social Justification of Advertising and Promotional Expenditures

According to the brief of the Canadian Pharmaceutical Manufacturers Association, the pharmaceutical manufacturing industry has four main areas of responsibility: to develop new and improved forms of medication and to discover and improve methods of producing them; to manufacture under controlled conditions ensuring uniformity, safety and therapeutic effectiveness; to distribute these products and maintain supplies; to make the professions aware of new discoveries and improvements (Hearing, pp. 1922-23). The following comments were also made in the brief:

"These four stages are interdependent, in that they comprise a chain of continuity which ensures the nation of a constant supply of the latest and most effective medication available. No single stage is sufficient unto itself, without the other three. Nor can one stage be dropped without materially affecting the efficiency of the system, which is one of the finest of its kind in modern society.

This chapter deals with the communication stage, referred to as advertising and promotion. This area of endeavour has been subject to much criticism. Yet it is vitally important to the physician who must in the best interests of his patients keep abreast of the latest progress in pharmaceuticals. It helps to reduce the time lag between discovery of a product and its uses in medical practice.

It has been said that 70 per cent of today's medical practitioners completed their internships at least 10 years ago, when penicillin G, streptomycin and the toxic mercurial diuretics were the newest substances known. Many of the medicaments which these doctors learned about from their courses in materia medica have since become obsolete. The decade has brought with it the psychosomatic drugs, new steroids and new muscle relaxants, to name but a few major advances which have occurred in this brief span of time.

Accordingly, advertising not only promotes the companies' products but it also fills a real need by keeping the doctor informed of current developments in the field of pharmaceuticals. . . ."

(Association brief, p. 57;
Hearing, pp. 1923-24)

Mr. S.N. Conder, General Manager of the C.Ph.M.A., testified further as follows:

"MR. CONDER: Mr. Chairman, when a new product, for example, is first introduced to the market the important thing from the viewpoint of the marketing company is to get that product brought to the attention of the doctor first, so the doctor is aware here is a new antidepressant, for example. It is then for the doctor to find more information on it. In this case the initial job of the company is to bring it to the doctor's attention so the doctor is aware of the product and the name of the product. The doctor may be using another form of antidepressant at that particular time and it may not make an impact on him. He may be quite happy with the antidepressant he is using, but at the same time he may feel he would like to get further information on this particular product to compare it with his own experience in other products. . . ."

(Hearing, pp. 1927-28)

A pharmaceutical manufacturing firm's advertising and promotion of a new drug aims at persuading the medical practitioner to prescribe the new drug in his treatment of a particular disease or diseases. If there are other drugs available for the treatment of a particular disease, the purpose of the advertising is to persuade the doctor to use the new drug because of its allegedly superior curative effects or because of the allegedly reduced incidence of toxicity or side effects attendant upon its use. Thus much of the pharmaceutical manufacturers' advertising and promotion is implicitly competitive in nature. At times the pharmaceutical manufacturing firm may promote a new drug that competes with one of its established products. An example of this is the introduction of Achromycin dealt with as follows in the brief of Cyanamid of Canada Limited:

"Three years after the end of the war, American Cyanamid developed and marketed the first of the broad spectrum antibiotics, chlortetracycline, under its trade name, Aureomycin. This drug represented a revolutionary advance in medicine and was effective against a far broader range of infective organisms than had been any previous drug. . . .

. . .

Aureomycin, however, had certain drawbacks. Unless substantial dosages were administered to the patient at frequent intervals, the activity of the drug would decline too rapidly in the body to deliver its optimum effect. The larger the dosages, on the other hand, the greater the risk of toxicity to the patient.

Faced with these problems, and with severe competition from other broad spectrum antibiotics, American Cyanamid in 1953 developed a superior broad spectrum antibiotic, more stable and less toxic than Aureomycin - namely, Achromycin, tetracycline. It was more effective in penetrating certain critical body tissues and fluids, such as those of the brain and spinal cord, which made it the drug of choice in the treatment of meningitis.

Achromycin was considerably more expensive to make than Aureomycin. Introduction of the new product to the medical profession required very heavy promotional expenditures which would have justified a price far higher than its predecessor. Pricing policy had to take into account the fact that although the drug could have been introduced at a far higher price, its acceptance in that event would have been consequently delayed. It was introduced in Canada in February, 1954, under the trade name Achromycin at exactly the same suggested list price for a comparable quantity as Aureomycin: \$9.35."

(Cyanamid brief, pp. 34-36;
Hearing, pp. 1510-14)

Mr. R.B. Thompson, of Cyanamid of Canada Limited, testified further as follows:

"MR. WHITELEY: What would be the elements of the very heavy promotional expenditures?

MR. THOMPSON: Here was a new drug, Mr. Whiteley, offered to the medical profession in the face of an already widely accepted and trusted antibiotic, and the burden was on our company to show that the new Achromycin had sufficient advantages over Aureomycin to justify a replacement in the mind of the physician. This is a costly and difficult method or form of promotion because physicians generally are very reluctant to abandon something that works well for them.

MR. WHITELEY: I wondered how you would proceed in that case?

MR. THOMPSON: We offered samples on a broad scale, hoping the physician would try the new drug and compare it with others he had used, including Aureomycin. We sent salesmen to see the doctors with visual material; we used direct mail advertising and extensive journal advertising."

(Hearing, p. 1514)

The social usefulness of the pharmaceutical manufacturers' advertising and promotional efforts depends in large part on the extent to which their advertising and promotion succeed in drawing the attention of physicians to new and useful drugs or new uses of previously-known drugs and also on whether it performs this function more effectively than available alternative methods of disseminating information.

2. Social Value of Advertising in Journals

In addition to carrying articles on drugs, journals also carry the actual advertisements of drug companies. The purpose of advertising in journals was explained as follows in the brief of Cyanamid of Canada Limited:

"The principal purpose of medical journal advertising is not to try to teach the doctor about the drug, but to remind him of its existence and sometimes to make suggestions which may lead him to consult the more complete information which is readily available. The busy practitioner, unless reminded of drug products through journal advertising, may overlook the suitability of a particular drug for a particular disease."

(Cyanamid brief, p. 24;
Hearing, pp. 1495-96)

Judgment on the social value of this form of advertising must take cognizance of the fact that the journals are partially or wholly supported by the advertising revenues earned by the publication. It should also take into account the quality of the information presented in the actual advertisements themselves. On this question, the following comments were made in the brief of the Canadian Pharmaceutical Manufacturers Association:

"Medical journal advertising is also another important source of information for the doctor, yet it has been criticized as being flamboyant, misleading, and with no mention of contraindications. It is a known fact that most Canadian journals carefully screen the copy for advertisements prior to insertion. It is also common practice for all major companies to have their copy reviewed by physicians before it is sent to the journals. In some cases, the copy is written by doctors, or, in the case of a new discovery, by a medical advertising specialist in collaboration with the company's director of research.

Visually, the so-called flamboyant pictorial style used in journal advertisements is not as unusual as it may appear to the uneducated eye. An advertisement to gain readership must be more than a box of black type. It must carry a pleasant layout of copy, and to a higher intellect such as a professional man this layout must be in extremely good taste.

Secondly, it is usual practice to include in the advertisement a picture or design to improve the type layout. In journal advertising, the picture used invariably is intended to depict in some form the medical problem involved.

As a general condemnation of advertising copy has been submitted to this Commission, we have attached to this submission a copy of the August issue of *Applied Therapeutics*, and we would ask you to review with us some of the advertisements in this journal, . . .

. . .

. . . This journal is published by a commercial house as compared with a medical society organ. But regardless of the implication left with this Commission by one witness, [1] there is no difference whatever between the advertising which appears in this publication and that of the *CMAJ*, for example. Although commercial in nature, this journal has a high professional standing. Not only are its national board and consultants drawn from among some of the senior medical authorities in Canada, but its editorial board of independent physicians reviews the advertising which appears in the book."

(Association brief, pp. 60-63;
Hearing, pp. 1939-40; 1946-47)

[1] *Applied Therapeutics* had been classified as a trade journal by Dr. J. P. Gemmell, Associate Professor of Medicine at the University of Manitoba (See section 2 of Chapter XIII)

The Commission has examined the August, 1961 issue of Applied Therapeutics (Exhibit T-8). The persons on the editorial board, drawn from medical and scientific fields, include members with national standing. As to the advertisements, the frequency of some of their leading characteristics is indicated in Table 14.

Table 14

Characteristics of Advertisements
in Applied Therapeutics,
August, 1961

	<u>Number of Instances</u>
1. Total number of advertisements	38
2. Brand name given	38
3. Generic name given	29
4. Chemical name or diagram of molecule given	2
5. Indications given ⁽¹⁾	32
6. Contraindications mentioned ⁽²⁾	5
7. Specific side effects named or the existence of unnamed side effects suggested	11
8. Name of at least one ingredient given in the case of compounds	12
9. Information on dosages	17
10. Information on available dosage forms	31
11. References to medical literature	8
12. Journal article reprints, brochures or descriptive material available	9
13. Samples sent on request	3

As expected, these advertisements addressed to doctors are free from any appeal to the profit motive. They are also uninformative on actual costs or prices except in vague and imprecise terms. For example, two of the advertisements refer to the advertised drug as "economical" (pages 643, 645); one (page 619) says "sensibly priced to your patients"; one (page 645) says "older patients, whose funds are often limited, will particularly welcome the low cost of . . . therapy"; another (page 623) claims that the process used in the development of the product "made acid-protection available without resorting to the more costly penicillin salts".

(1) i.e. conditions or diseases for which the drugs are to be used.

(2) i.e. conditions or ailments in the presence of which the use of a drug is to be avoided.

The Commission has made an examination of the advertisements of drugs appearing in the March, 1962 issue of Drug Merchandising. In addition to drugs the examination also included advertisements for weight-control foods, vitamins, mineral foods, and dental aids. Altogether 20 advertisements have been studied. Their characteristics are shown in Table 15. With regard to item 5, the indications were usually of a very general nature; for example, the drug advertised on page 11 is said to be "for effective cough control"; that on page 4 is a poultice "for sore, tender, inflamed gums". Typically there is no mention in precise medical terms of the ailment for which the drug or preparation is intended. With respect to item 10, the information is not precise, often consisting merely of the indication that the product or products are available in the form of tablets, salves, syrups, capsules, powders, or wafers. Seldom is the exact amount of drug(s) present in a given tablet stated. Finally, of the total of 20, 16 had one or more of the types of information or appeal described in items 14, 15 and 16 of Table 15.

Table 15

Characteristics of Advertisements
in Drug Merchandising,
March, 1962

	<u>Number of Instances</u>
1. Total number of advertisements studied	20
2. Brand name or trade mark given	19
3. Generic name given	3
4. Chemical name or diagram of molecule given	0
5. Indications given	11
6. Contraindications given	0
7. Specific side effects stated or existence of unnamed ones suggested	0
8. Name of at least one ingredient given in the case of compounds	4
9. Information on dosages	0
10. Information on available dosage forms	11
11. References to medical literature	0
12. Journal articles, brochures, descriptive material, etc. available	1
13. Free samples available	2
14. Costs, retail prices, profits, or profit margins mentioned	11
15. Special deals indicated	5
16. Other profit appeals	10

The advertisements in Drug Merchandising differ markedly from those in Applied Therapeutics in several ways. Drug Merchandising contains less information, or less precise information on indications, contraindications, side effects, dosages, dosage forms, chemical or generic names, and contents of mixtures. On the other hand, its advertisements generally have precise price information and a marked appeal to the profit motive; those in Applied Therapeutics lack both.

The Commission also made an examination of the advertisements of drugs contained in the March, 1961 issue of the Canadian Pharmaceutical Journal. Their leading characteristics are shown in Table 16. As was the case with the March, 1962 issue of Drug Merchandising, these advertisements usually gave general rather than specific information on some of the matters listed in Table 16. The indications were usually of a broad, imprecise nature, and the information on dosage forms was often limited to an indication of whether the drug was available as a powder, tablet, liquid, capsule or candy. Ten of the fifteen advertisements had one or more of the types of appeal to the profit motive described in items 14, 15 and 16 of Table 16.

Table 16

Characteristics of Advertisements
in Canadian Pharmaceutical Journal, March,
1961

	<u>Number of Instances</u>
1. Total advertisements studied	15
2. Brand name given	14
3. Generic name given	5
4. Chemical name or molecular diagram given	0
5. Indications	9
6. Contraindications	1
7. Side effects indicated or suggested	0
8. Name of at least one ingredient given in the case of compounds	3
9. Information on dosages given	1
10. Information on available dosage forms given	9
11. Reference to medical literature	0
12. Journal articles, brochures, or descriptive material available	1
13. Free samples available	0
14. Costs, profits, or profit margins mentioned	2
15. Special deals indicated	1
16. Other appeals to profit motive	10

The question of the suitability in a professional journal of such appeals to the profit motive has been dealt with as follows in the briefs submitted by:

(a) Nordic Biochemicals Ltd.:

"... Any issue of the Canadian Pharmaceutical Journal shows that preoccupation with the purely commercial side of the profession receives a large measure of editorial attention, and certainly is the theme of practically all the advertisements directed at the practising pharmacist. As an example, the March 1961 volume of this publication contains 21 full pages of advertising. Most of these advertisements are by drug manufacturers. Those that deal with specific products emphasize the profit advantage in 'pushing' the product concerned. The phraseology is illustrative of this and the following are examples, each culled from a separate advertisement in this issue: 'High margin medication' - 'You profit from rapid turnover and repeat business' - 'New profits to you' - 'Another profit producer' - 'Traffic builders for you' - 'Another potential best seller' - 'Recommend them for increased profit' - 'Cash in on these... deals' - 'Leading seller' - 'High profit... products'. The whole tone of advertising directed at the retail pharmacist is well summarized on the back cover ad of this issue: a list of the advertiser's products are set forth in an attractive box whose border is formed of \$\$\$\$ signs!

The druggist who is striving for professional stature would do well to compare the advertisements to which he is exposed in his own trade journals with those that the same drug manufacturers place in the journals directed at the medical profession. In the latter, advertisements suggesting that the reader will derive material profit from prescribing a specific product is, of course, unheard of, and every pharmaceutical manufacturer knows that such ads will be rejected out of hand by the editorial board of every medical journal. It is obvious that the profession of pharmacy will never achieve its desired stature unless it is prepared to accept ethical restraints similar to those imposed by the medical profession on its own membership."

(Nordic brief, pp. 12-13;
Hearing, pp. 1399-1401)

(b) The Canadian Pharmaceutical Association, Inc.:

"Advertisements in The Journal are directed to the

practising pharmacist and, as opposed to those for the same products which appear in, for example, the Journal of the Canadian Medical Association, place more emphasis upon business proposals than upon advantages to be gained by the medical use of the preparation. This may not be 'considered' altogether correct, but it is certainly part of the practical information the practising pharmacist must have. Advertising respecting non-prescription items naturally attempts to woo the business of the retail dealer by placing emphasis upon special deal profits, including the use of \$\$\$ signs which, to some, during the past year or so, have become repugnant. This is not a situation which has developed over the past few years. Similar advertising, written in the language of the day, is found in the Canadian Pharmaceutical Journal of the late 1800's.

Advertising revenue is, of course, important to the Association's publication and this is reviewed each year in setting our budget. During the 1960 calendar year 25 pharmaceutical manufacturers (i.e., C.P.M.A. members) used 110.5 advertising pages, with the balance of the 270.5 page total being used to advertise patents and proprietaries, 50 pages
cosmetics, 13 pages
fixtures, 32.5 pages
photographic, 14 pages
others, 50.5 pages"

(Association brief, p. 103d;
Hearing, pp. 2588-89)

On this point, the following additional evidence was given to the Commission by:

(a) Mr. K. Antoft, President of Nordic Biochemicals Ltd.:

"THE CHAIRMAN: There is a difference, the doctors are not selling the drug. The druggist is.

MR. ANTIFT: Yes, but the appeal of the manufacturers to the druggist is if you sell this drug you will make a profit. The manufacturer does not appeal to the medical profession on the same level.

THE CHAIRMAN: It appeals to the medical profession on the basis if he prescribes this drug it will be beneficial for his patient.

MR. ANTOfT: That is correct, and I think we could very well, as manufacturers, we could very well adopt for ourselves the same kind of tactics in our advertising directed at the pharmacists. We, as manufacturers, are anxious that the pharmacist shall retain or build his professional stature. I think we are debasing him by appealing solely to his commercial motives in doing business. I think that the pharmacist has a role in easing and helping the doctor to assess new products, but if he is overwhelmed with this type of promotional approach this pharmacist is very likely to put commercialism ahead of what he would otherwise do to influence the doctor in prescribing the newer developments in drugs. He has more time to follow them than the doctor has. This is the point that I am trying to make in this section. I think this has come about both by the manufacturers and the retail druggists being somewhat lax in this respect and have allowed this situation to develop over the years."

(Hearing, pp. 1401-02)

(b) Mr. R.B. Thompson, Manager of the Medical Products Department of Cyanamid of Canada Limited:

"MR. WAHN: I believe statements have been made, Mr. Thompson, to the effect -- and this is in relation to the controversy between brand names and generic names -- that manufacturers in Canada tend to over-emphasize to the retail druggist the profit they can make by selling brand name drugs, thus creating favouritism on the part of druggists who use brand name drugs rather than generic name drugs.

Would you care to comment on this suggestion?

MR. THOMPSON: I would indeed. I think Mr. Antoft mentioned the March 1961 issue of the Canadian Pharmaceutical Journal, and indicated in his testimony that most of the advertising was oriented towards the profit the pharmacist could make on ethical products.

I don't believe he read the journal thoroughly, because this issue, and I would be glad to leave it with the Commission, contains 14 advertisements which mention the words 'Profit' or 'Dollars' or similar expressions. Only four of those advertisements were placed by ethical manufacturers, and out of those four, three were for over-the-counter items. That is, items which do not require prescriptions, where the druggist can make the sale by his own effort.

All of the other profit-mentioning advertisements were placed by proprietary houses or advertised non-drug items. In other words, items which do not require the intervention of a physician, so that I suggest it is not customary or desirable or even effective for an ethical pharmaceutical manufacturer to suggest to the pharmacist 'You can make more profit by selling my product than somebody else's'."

(Hearing, pp. 1549-50)

(c) Mr. J.C. Turnbull, Secretary-Manager of The Canadian Pharmaceutical Association, Inc.:

"MR. CARIGNAN: Just one more question. Would it not be appropriate for your Association to put a check on the kind of advertising which, it is admitted on page 103d, appears in the Journal and is primarily emphasizing the profit advantages?

MR. TURNBULL: I don't have separate copies of the Journal with me, but I would be very pleased, sir, to make available to you the Journal that Mr. Antoft made specific reference to, and even a cursory review of Mr. Antoft's references to costs and that type of thing, even a cursory review will indicate that he is quoting out of context. I didn't want to say this, but I am afraid it is correct. Now, relative to our policy concerning the acceptance of advertising in the Journal we attempt to temper the advertising message where, in our humble opinion, it is not quite right, shall we say, but we don't force our will upon the advertiser. If it is necessary to force our will upon him we are in the position we don't accept the ad and therefore the ad does not appear.

MR. CARIGNAN: In many advertisements in the issue that has been filed with the Commission, the rate of profit is indicated as the main factor, for instance: 'Sell this kind of pill, the rate of profit is so much.'

MR. TURNBULL: That is pertaining to items that are available for sale without prescription.

. . .

MR. CARIGNAN: Here, for instance, in the issue of September, 1961, page 83. . . I see 'Cash in on these profitable drugs' . . . then at the bottom 'Order now, quick profits, fast turnover'.

MR. TURNBULL: I have a basic knowledge of these two particular products. One is a toothache remedy, the other dental poultice. It states right on there number so-and-so under the Proprietary or Patent Medicines Act and it contains 3% benzocaine and other ingredients. These are available any place, anywhere at any time without any supervision whatsoever. It is strictly a merchandising proposition.

MR. CARIGNAN: In that the pharmacist is expected to guide the customer - these products are bought without prescription and a pharmacist is expected to guide the customer. Now, he should advise the customer to buy one kind of product because it is best, not because it is more profitable for him to sell that kind and not another kind.

. . .

MR. TURNBULL: . . .

I don't believe that you will find that type of measure concerning what we choose to call 'pharmaceuticals', with certain exceptions, of course. In that same issue, page 79, in which Merck is indicating how good Crystalline Vitamin B is, you will find the commercialized type of advertising in the inserts just ahead of the survey as well, a combination deal with a chest rub proposition and a fixture manufacturer, but it is related to modernization by fixtures as well as selling, and the pharmaceutical advertising again on page 25.

MR. CARIGNAN: Here no price appears on this one, and it is quite all right, but the others I see they tell what will be the profit for the druggist, or at least they indicate that the profit may be so much.

MR. TURNBULL: Yes.

MR. CARIGNAN: And the druggist surely is able to calculate himself what profit he will make. I think that such appeals should not be made . . . to a profession, especially in the Journal of the Association.

MR. TURNBULL: Of course we have to consider that these profit appeals and that type of thing, sir, are related to the business side of the pharmacist's business establishment. They are not necessarily related to the items that he will use in his dispensary to meet the prescription demands. These pertain to, shall we say,

front store, or front counter selling items. I would be the very, very first to agree with you, and this is not a new story. We have debated this very often in our own Committees relative to the desirability of certain pieces of advertising and that type of thing.

Regrettably associations such as ours and such as I imagine just any other association has to face the cold hard fact that we have to have a certain number of dollars to assist us in the publication of our magazine. At the same time we realize that this price information as contained in advertisements concerning profits and what not, does have value to the retailer. At the same time it enables us to publish a magazine which we hope will advance the retailer's work in his community.

There is no question that we whole-heartedly agree with you that it would be most desirable to never mention these nasty terms of 'plus 10% bonus profit', and this type of thing, but it enters into the field of commerce. We don't really think that a discussion in an advertisement of that type of profit and profit structures, provided it is not blatantly thrown about, is to be discouraged in the field of commerce today.

I am sorry I can't possibly give you a more specifying answer to what you are seeking, but there are so many things involved in the acceptability and the acceptance of advertising messages."

(Hearing, pp. 2813-18)

3. Distribution of Samples as a Danger, a
Waste or a Useful Practice

Is the drug manufacturers' practice of making free sample available to doctors dangerous, wasteful or useful to society? On this matter, the brief presented by Cyanamid of Canada Limited contains the following passage:

"There has been testimony before this Commission that the practice of distributing free samples of drugs to physicians is a wasteful one. But samples have a great many uses for the doctor. In the first place, it is important for a doctor to be personally acquainted with a new drug and its results before he prescribes it with confidence.

Another important use of samples is for initial dosage. There is no drug which can be tolerated equally well by all patients. Doctors find samples extremely useful for beginning treatment with the patient whose ability to tolerate the drug has not been established. Doctors also like to have samples in their bag so that they can begin treatment immediately at times when there may be delays in filling prescriptions through a drug store - for example, in making house calls at night. This is particularly true for drugs such as antibiotics which are used to combat serious infections.

Furthermore, doctors frequently use samples in the treatment of patients in poor financial circumstances.

It is no doubt true that samples of some kinds of drugs are more valuable than other kinds to the doctor. Cyanamid does not sample all its drugs indiscriminately but is guided in accordance with what it finds doctors want. We have no doubt that the great majority of practising physicians welcome and use our samples and would not want us to discontinue them."

(Cyanamid brief, pp. 25-26;
Hearing, pp. 1497-98)

Furthermore the policy followed by Cyanamid of Canada Limited was described as follows by Mr. R.B. Thompson, Manager of its Medical Products Department:

"MR. THOMPSON: We don't sample Aureomycin except in rare cases. Sampling generally has regard for the circumstance in which the sampling is done. In other words, I think I referred to the case of the Dale family in Ottawa, and in that situation we furnished substantial sized packages of Aureomycin syrup.

A physician who expresses an interest in applying one of our antibiotics to a treatment, to a specific patient, generally receives a sample commensurate with his need in that situation. A very frequent size is a bottle of 16, for Declomycin in particular.

MR. MacLEOD: Have you sampled tetracycline lately?

MR. THOMPSON: Yes.

MR. MacLEOD: What would be the normal sample that you would furnish a physician?

MR. THOMPSON: There are again samples, packages of 16, and it is also available in other dosage forms, injectable and liquid dosage forms also."

(Hearing, pp. 1690-91)

On the usefulness of sampling, the brief of the Canadian Pharmaceutical Manufacturers Association read as follows:

"Sampling is another practice followed by the industry when introducing products to physicians. The objective is to give these to doctors so that they can evaluate the drug's usefulness. These samples are often given to patients as 'starter doses' to be used until the patient can have a prescription filled. A number of physicians use samples for their indigent patients, and some companies actively support this practice.

The tables on pages 108-110 of the green book show a considerable variation in the percentages of sampling costs to sales. We are reasonably certain that the higher percentages reflect more costly products such as the antibiotics. And these product samples are the very ones which the doctor will keep in his bag for night and emergency calls. Doctors do use samples, and it would hardly be practical to expect the physician to buy these products himself."

(Association brief, p. 67;
Hearing, p. 1964)

Questioned about the usefulness of samples freely distributed to them, three practising physicians expressed widely varying views as follows:

(a) Dr. Nathan Schechter, Chairman of the Pharmacy Committee of the Ottawa Civic Hospital:

"MR. MacLEOD: . . . What have you to say about the practice of distributing samples to doctors? Is it wasteful, is it helpful, just what is the situation?

DR. SCHECTER: I think probably the majority of it is wasteful. The majority of it is not used for any useful purpose and again has to be discarded. Some of it is of value in giving to patients to help reduce their costs, especially in the more expensive items. . . .

. . .

MR. MacLEOD: As far as you personally are concerned, doctor, could the drug companies cut out samples and still enjoy your business to the same extent they do now?

DR. SCHECTER: I think so, I believe so.

MR. MacLEOD: It wouldn't affect the products which you prescribe?

DR. SCHECTER: No."

(Hearing, pp. 271-72)

(b) Dr. J.W. Reid, practising in the City of Halifax:

"MR. MacLEOD: What about the practice of the manufacturers distributing samples to doctors? Do you find the provision of samples to you helpful in your work?

DR. REID: Well, it is helpful in this way, particularly. We are actively engaged in the practice of medicine. New preparations are made with which we are not familiar. We cannot go back to our medical school's pharmacology laboratory and see these things made or learn about them directly, and we are obliged to become familiar with these drugs through the samples that the drug people send to us. It enables us to recognize the drug, whether it be a tablet or capsule and become familiar with it in that way. Otherwise we would have no idea, if we finally did decide to prescribe a new preparation for a patient, we would have no idea whether the patient was getting the exact material unless we had previously seen it and knew what it was like.

The amount of sampling is not very great actually. The number of tablets that come in demonstrating a new drug does not amount to very much. It is just enough to familiarize us with it and that is all.

MR. MacLEOD: In your experience in the provisions of samples to you, do they serve a useful purpose?

DR. REID: It serves a useful purpose, indeed it does.

THE CHAIRMAN: Do you actually make use of the samples in your practice?

DR. REID: I make some use of them, yes. In my emergency bag I carry some of these samples and try them,

and those that are not used in that way are used in some other way. They are distributed to the local clinics or sent in gross into some place where they might be used.

THE CHAIRMAN: They are not simply thrown away?

DR. REID: No they are not thrown away."

(Hearing, pp. 389-91)

(c) Dr. J.P. Gemmell, Associate Professor of Medicine at the University of Manitoba:

"... These [samples] actually come from one of our offices, and we have three or four large packing cases like that; the secretary just throws the samples in. It may be that we doctors, I think, as a rule tend to use the samples perhaps as trials on people; sometimes they save them for people who can ill-afford medication. It is given in that way, and in other particular situations many of us who receive the mail centrally at the College, there is a box like this, and we take them and give them to the patients at the out-patients' pharmacy department."

(Hearing, p. 505)

On this point, the general view of pharmacists was expressed in the brief of The Canadian Pharmaceutical Association, Inc.:

"The problem of sampling which, on many occasions, appears to be wasteful and, in some instances, dangerous, is befitting of our concern. Overly generous sampling procedures sometimes cause a deterioration in the relationship between physician and pharmacist, as well [as] poor public relations with the patient. Samples bearing original labels given to a patient often result in demands for repeat medication which cannot be supplied without a proper prescription. If the demands can be met by prescription or otherwise, the preparation often appears expensive in the eyes of the patient who initially received them without charge. This is a public relations problem, of course.

The pharmacist's greatest concern relates to the sampling of prescription-only drug items and the inherent dangers arising from the mishandling of such samples. They may, for one reason or another, find their way into the hands of the lay public, or worse, into the hands of children. Our Association has frequently recommended 'That sampling be done only to those physicians or

institutions who request a quantity of the preparation for experimental or investigational purposes.' The provision of samples to members of the health professions is a legal procedure under the Food and Drugs Act. Unsolicited samples could be voluntarily restricted to minor quantities sufficient to establish the physical identity of the preparation referred to in medical information pieces which they accompany."

(Association brief, pp. 34-35;
Hearing, pp. 2362-63)

Mr. J.C. Turnbull, Secretary-Manager of the C.Ph.A., testified further as follows:

"THE CHAIRMAN: Can you tell us more about how seriously you regard that situation? As I understand it, sampling is made to members of the medical profession.

MR. TURNBULL: In the main, sir, yes.

THE CHAIRMAN: Do you think there is any great danger of drugs that are given to members of that profession as samples being dealt with carelessly?

MR. TURNBULL: Yes, I think so. It is less than two years ago that there was a very serious case where children apparently got into one of the community nuisance grounds in the Toronto area and apparently got their hands on some samples that had been thrown out in garbage from a doctor's office, and there were rather serious consequences.

I don't have that document, by the way, but I do recall the small panic at that time. I also know that there are instances where these things have been found in some quantity in garbage cans, but I could not tell you the type of sample they are.

. . . We know, too, that samples are used by physicians to help needy people and that type of thing."

(Hearing, pp. 2363-64)

4. Informational Value of Direct Mail

The informational value of direct mail to doctors has been described as follows by Mr. S.N. Conder, General Manager of the

Canadian Pharmaceutical Manufacturers Association:

" . . . It is in that particular area the company is very helpful. They produce, I would say, invaluable product brochures which explain this product in complete detail, they have complete clinical information and frankly in some cases or in most cases the clinical information contained in these brochures is even more extensive than some of the information which may appear in an article or a research paper published in a medical association journal because the journal is naturally limited to the amount of space it can give whereas the company can put in complete information, give full details of side-effects, toxicity and other factors in their brochure which is made available to the doctor."

(Hearing, p. 1928)

With respect to information on side effects and toxicity, the brief of Cyanamid of Canada Limited stated:

"There has been much criticism that toxicity and side-effects are not sufficiently known by the members of the medical profession. Our index cards^[1] supplied to physicians contain completely adequate statements as to the possibility of side-effects, which statements are in no way attempts to 'gloss over' these side-effects (as was indicated in earlier testimony before this Commission).

Furthermore, it is far better to disclose than to conceal side-effects, for otherwise the drug product and the drug manufacturer would soon become regarded with distrust."

(Cyanamid brief, pp. 23-24;
Hearing, pp. 1494-95)

Even if a great deal of accurate information is contained therein, direct mail advertising has no more social value than the drug that is advertised or promoted. In this respect, Mr. K. Antoft, President of Nordic Biochemicals Ltd., gave the following evidence:

[1] An index card for Declomycin (Exhibit T-1) was filed as an example.

"MR. MacLEOD: In your opinion as the man in the industry, has this power been used, has money been spent on advertising products where, in your opinion, it shouldn't have been spent or as much have been spent on the particular product?

MR. ANTOST: Yes, I usually -- our medical consultant periodically delivers up to us samples of his mail for a week or so. I would say there is a great deal of it is just trivial in the type of thing it is trying to promote. . . ."

(Hearing, p. 1439)

Whatever be the intrinsic value of direct mail to doctors, this form of advertising may be wasteful if doctors are buried under such a volume of promotional material that the bulk of it is not read. For this reason some evidence regarding the volume of direct mail received by doctors is relevant. In this respect, Dr. J. P. Gemmell, Associate Professor of Medicine at the University of Manitoba, testified as follows:

"THE CHAIRMAN: . . . You have given a number of items, some of which are samples, some were journals, and you have taken a good many of them from a large carton on the table. Can you tell me how long it would take to accumulate samples of literature of that kind like that?

DR. GEMMELL: I have no factual information, but I think if you talk to most doctors, you get one wastepaper basket full a day, if you pile them all in one wastepaper basket, come reasonably close to filling it.

THE CHAIRMAN: Every day?

DR. GEMMELL: Every working day, that is.

THE CHAIRMAN: Doctors work seven days a week.

DR. GEMMELL: There are somewhere around 4,500 pieces of direct mail received by the physician in the United States each year.

THE CHAIRMAN: How much?

DR. GEMMELL: 4,500.

THE CHAIRMAN: 4,500 pieces of direct mail advertising literature per year.

DR. GEMMELL: And when you get some of them this size, they can fill up a wastepaper basket easily.

THE CHAIRMAN: That is in the United States.

DR. GEMMELL: I don't know of any real study of this that has been done on the exact number, but I am sure it is not too dissimilar.

THE CHAIRMAN: In Canada?

DR. GEMMELL: Yes."

(Hearing, pp. 509-10)

With respect to the above quoted evidence, the brief of the Canadian Pharmaceutical Manufacturers Association contains the following comments:

"... we wish to comment briefly on a couple of statements made before this Commission by Dr. J.P. Gemmell in Winnipeg.

This witness stated that physicians in the United States receive about 4,500 pieces of direct mail per year and that the amount in Canada is not too 'dissimilar'. We do not know whether the U.S. figure is authentic, but we do have evidence which shows conclusively that the amount in Canada is less than half that figure.

According to the Medical Mailer for March, 1961, produced by Canadian Mailings Ltd., of Toronto: 'The English speaking doctor (in Canada) received a total of 2,147 pieces of mail advertising during the year 1960.' Nor was all of this literature from pharmaceutical houses. The same reference indicates that 18 per cent of this literature was from suppliers of books, journals and equipment, plus general solicitations. Deducting this 18 per cent from the total mailings received by a doctor in the course of a year means that he actually received 1,761 pieces of literature from pharmaceutical houses, which most certainly is a far cry from 4,500."

(Association brief, pp. 69-70;
Hearing, pp. 1967-68)

Representatives of the medical profession took a critical attitude towards direct mail as appears from the evidence given by:

(a) Dr. Nathan Schechter, practising doctor and Chairman of the Pharmacy Committee of the Ottawa Civic Hospital:

"MR. MacLEOD: Do you receive a large volume of advertising, promotional and informative material, from the manufacturers?

DR. SCHECTER: Yes, there is a great deal of it.

MR. MacLEOD: Is the volume such that you have difficulty in coping with it and reading it all?

DR. SCHECTER: It is impossible to read it all.

MR. MacLEOD: What happens to what you can't read?

DR. SCHECTER: Discard it.

MR. MacLEOD: Can you give the Commission any idea of the value of that literature to you as a doctor?

DR. SCHECTER: Well, I think that there are some of the companies who put out very sensible, well-written documented articles on their drugs. There are others - and one realizes it when reading them - that probably these have been written by the advertising departments rather than the medical directors of the firm, because they are couched - the same thing when you are buying soaps or detergents or things like that; it is blatant advertising and sentences taken out of context, and one cannot believe that type of advertising. But there are some companies who put out very valuable information.

MR. MacLEOD: That is what I was going to ask, doctor. Do you find that certain companies consistently - let me put it another way. Do you find that the literature that you receive from X company, say, can generally be relied on?

DR. SCHECTER: Yes. Those are saved in certain companies [sic]. They send literature which I save for reading at my leisure and so on, but other companies we automatically discard, and very often it doesn't even come to my desk.

MR. MacLEOD: You would tend to cull out the information you regard as valuable and read it.

DR. SCHECTER: Yes. But I would say we rely on our better medical journals for the real information on drugs.

THE CHAIRMAN: Doctor, I was going to ask you about that. In answer to the last question but one, as you cannot possibly read all of the literature you are inclined at least to read the literature from the companies you think are dependable rather than the others.

DR. SCHECTER: Yes.

THE CHAIRMAN: Unless you are called upon to check up what someone has been doing.

DR. SCHECTER: Yes, that is the situation.

THE CHAIRMAN: You have to select.

DR. SCHECTER: Yes, one has to select.

THE CHAIRMAN: Do you have to discard the great majority that comes in?

DR. SCHECTER: Yes."

(Hearing, pp. 249-51)

"MR. BUCHANAN: Coming down to the literature, I understand, and I know you are bombarded with great masses of it. What percentage would you say, Dr. Schecter, perhaps is wasted, 50, 75, 90 per cent?

DR. SCHECTER: About 75 per cent."

(Hearing, p. 269)

(b) Dr. C.H. Reardon, practising doctor in the City of Halifax and Member of the Legislative Assembly in the Province of Nova Scotia:

"MR. MacLEOD: What about the literature that you receive from the drug manufacturers and drug distributors?

DR. REARDON: I think about 90% of it that you receive in the mail finds its way into the waste basket without even being opened.

MR. MacLEOD: Why should that be?

DR. REARDON: The same literature that you receive in the mail, you can receive from your medical journals and the advertising in the journals -- I would presume that

there is more selectivity about the advertising in the medical journals and I would read them.

. . .

MR. MacLEOD: And are there any particular companies that because of your experience with their material you look upon their material as being extremely valuable, or anything like that?

DR. REARDON: I think the Canadian Drug companies pretty well without question -- and I am speaking now of the drug companies that have been here for years -- which are large companies and you learn to respect them over the years.

MR. MacLEOD: Yes?

DR. REARDON: I think they are all of value.

MR. MacLEOD: I was wondering if there were, if this might be possibly the situation that if you see something from X company that you would have a tendency to put that aside and perhaps make an effort to read it because you would regard X company's information as being particularly carefully prepared, or is there anything like that?

DR. REARDON: I think that in the first place I have made the statement that we pitch out 90 percent without even looking at it. Therefore the ones that might catch my eye, that I do look at, they are all from pretty reliable companies and I think some of the material, certainly a lot of the material, is well worth reading, and of the remaining 10 percent, some of the companies send some very valuable literature around to the doctors. They will send around valuable literature such as dealing with emergency injuries, head injuries, injuries of the hand, injuries of the leg, put out in a very valuable manner so that it is easy to read and very informative and certainly of value to the doctor. That type of literature never gets pitched out. That is taken in and kept on file.

The type of literature that makes up the 90 percent -- and I use these percentages very roughly -- are the ones that come in small envelopes like letters that you just would not have the time to cope with and try to go through."

(Hearing, pp. 370-72)

(c) Dr. J.W. Reid, practising physician in the City of Halifax:

"MR. MacLEOD: Could you give us some idea of the value to you as a practising physician of the materials sent out by the drug manufacturers?

DR. REID: Well, there are so many different kinds of materials that come into each doctor from the drug manufacturer. The first thing he is likely to get is some rather loud bit of literature designed to draw his attention to this new preparation, whatever it may be. This type of advertising -- I am not sure that the drug trade is to blame for it, perhaps it is the advertising trade that is more to blame for it than the drug manufacturer. That is the first thing that comes to us, and then later come a number of reprints from medical journals and research laboratories sent to us by the manufacturer. Those contain valuable information, actually, and much of their material is sometimes taken from scientific journals and research establishments. They can be of great value. That is in the newer drugs particularly, the biological preparations, and the company sends with that material a very complete brochure covering the characteristics and its actions which is very helpful to men in active practice and is quite thorough research on that material.

MR. MacLEOD: Do you think that the material put out by some companies is more reliable, in your view than that put out by others?

DR. REID: Well, I don't know that I could answer that. Our reaction to this material is colored a little bit by the attitude towards the drug company concerned and we are -- some of it we resent because it so blatantly advertises a combination of old drugs which doesn't have any particular value in it, so far as I can see.

I would hardly be prepared at this moment to say this company's material was useless and another company's material was good. They all may try to put valuable literature on our desks, but much of it we don't -- we are not able to read. Too much of it has come in.

MR. MacLEOD: Does that mean the volume is simply too great for you to give attention to?

DR. REID: Yes, actually in my mail this morning the volume of literature from various drug companies was such I wouldn't have been able to come to this hearing if I sat down to read it. It would have taken at least half a day to read. That is not due to any one drug company. It is due to the fact there are now so many firms actually advertising in this field, many more than we had 15 or 20 years ago.

THE CHAIRMAN: Doctor, I wonder if we cannot get that pinned down a little bit. You said this morning there was enough advertising material on your desk to take half a day to read it. Does that happen every day, or is it an exceptional occurrence to have that much literature?

DR. REID: Actually that is almost a daily occurrence.

THE CHAIRMAN: Does that mean that in effect you can only read a very small part of it?

DR. REID: That is correct.

MR. MacLEOD: And the remainder is discarded, is it?

DR. REID: It is discarded."

(Hearing, pp. 387-89)

(d) Dr. J.P. Gemmell, Associate Professor of Medicine at the University of Manitoba:

"DR. GEMMELL: Yes, I will speak a little later on the direct mail advertising that comes into the office. I have only a few, because my secretary throws them away, because she said it makes me too irritable if I have to open them, and this is just a few that I picked up. I have an analysis done by a fourth-year student on the drug direct mail advertising that came in. This barely warrants reading."

(Hearing, p. 502)

"DR. GEMMELL: . . . If I could read this. This was a study of fourth-year students associated with the value of drugs, because one of the students thought it would be of interest to analyze the direct mail advertising that comes in. The direct mail advertising received by the physicians in the Department of Clinical Investigation, Winnipeg General Hospital, was collected during the last three months

of 1959. 200 pieces of advertising were withdrawn at random. In the case of exact duplicates, only one copy was used in the study. The student analyzed it according to his own lights, and perhaps it may be worth reading this.

One of the criteria for evaluation was product identification. 21.5% failed to state the official name of the product; indeed, some failed to state what the drug was at all, it just gave the trade name.

THE CHAIRMAN: You mean they didn't give the generic name at all?

DR. GEMMELL: That is right, or the clinical name, and many of them used the chemical name which is almost unintelligible except to the ultra-specialist in the field. The quality of the information, according to his opinion, was that it contained ambiguous statements in 80%, 62% contained statements that were directly misleading, 11.5% contained misleading claims of dose-related potency (this is a thing that is brought up in our article), 48% contained no mention of the toxicity or side effects. The other 37% were limited to vague generalities, and approximately 15% contained rather detailed information on toxicity.

THE CHAIRMAN: 48% contained no reference to toxicity, but the fact is that nearly all of them have some toxic effect?

DR. GEMMELL: I think it is fair to say, isn't it, Dr. Nickerson, that all drugs have potential toxicity, and this includes patent medicines. That is 95% of cases absolutely no information is available on the cost of the drug to the patient. The type of product advertised was a drug mixture, not a proper single drug, in 38.5%, and in his opinion 80% of the advertising, the illustrations, were either irrelevant or in bad taste.

THE CHAIRMAN: This was done by one fourth-year student?

DR. GEMMELL: Yes.

THE CHAIRMAN: Was there any check made at all to see what extent it could be relied on?

DR. GEMMELL: No, this was not done. I know from experience, without going through them - I have no doubt that these figures are correct. Actually when you consider that some of these things are quite objective, there is no reason for him to mislead us.

THE CHAIRMAN: It is not a question of misleading. A fourth-year student's report, it is not the medical practitioner with ten or fifteen years' experience.

DR. GEMMELL: You don't need to be very experienced to tell whether a drug is identified or whether there is a cost on the drug.

THE CHAIRMAN: Yes, but do you consider a fourth-year student was qualified to deal with that completely?

DR. GEMMELL: These were brought to their attention by different staff members. Dr. Nickerson brought it to their attention for their opinion, how they would judge this.

THE CHAIRMAN: From your own experience and knowledge of these matters, you are not surprised at the results, I take it?

DR. GEMMELL: No. I think it is a very fair analysis of it."

(Hearing, pp. 506-08)

"THE CHAIRMAN: With regard to this vast mass of material that comes in to a doctor's office, are you able to tell us what becomes of it? Do the doctors attempt to read it - I gather it is impossible to read it all - what do they do with it? Do they attempt to go through it pretty carefully?

DR. GEMMELL: Well, sir, it is almost impossible to keep up with even the properly published literature. Now mind you, I think one thing about this material that comes out of the drug houses in many ways; it is very highly professionalized in its production. It is almost more attractive sometimes to read even than it is to read articles in the regular medical journals, and it is particularly so because even if you look through them, they are beautifully illustrated, really have been excellently done.

THE CHAIRMAN: That is part of the business of a good advertising agent.

DR. GEMMELL: Yes.

THE CHAIRMAN: To produce literature which is attractive so that people will read it.

DR. GEMMELL: Yes but these even in discussing a disease, in which they may have no interest, no particular interest, can be very well done and by well-recognized authorities too."

(Hearing, pp. 516-17)

(e) Dr. F.B. Rodman, Assistant Clinical Professor of Therapeutics at the University of Alberta:

"MR. MacLEOD: Do you find the literature issued by the manufacturers useful to you in your work?

DR. RODMAN: What kind of literature?

MR. MacLEOD: The promotional literature, direct mail literature, that is mailed out to you?

DR. RODMAN: Maybe I can take that down a bit further. Some of the promotional literature that comes along with articles by other men I find valuable. The literature that comes along in a single page with a lot of red ink and so on, I merely pass over my desk into the trash can.

MR. MacLEOD: Can you make any estimate of the percentage of promotional literature which you receive which you find of real value?

DR. RODMAN: It is hard to put a percentage, I would say not very much.

MR. MacLEOD: Would over half of it go in the wastepaper basket?

DR. RODMAN: Oh, yes, yes. I might add in that respect that some of the drug representatives that do come around do give us concrete literature and drugs and papers that is a help, but I am referring strictly to material that is mailed."

(Hearing, pp. 905-06)

5. Usefulness of Detail Men to Pharmacists
and Doctors

Detail men are socially useful if they make pharmacists and doctors aware of new and improved forms of medication and if they provide information which assists the dispenser or the prescriber. To be able to do so, they must have a higher level of education than ordinary salesmen. In this respect, Mr. J.C. Turnbull, Secretary-Manager of The Canadian Pharmaceutical Association, Inc., said in his evidence, that years ago detail men were usually pharmacists, but that nowadays more are required than available with this qualification (Hearing, pp. 2365-67). This statement confirmed the following quotation from the brief of the Canadian Pharmaceutical Manufacturers Association:

"The educational requirements for a detail man are probably higher than that for salesmen in most other fields, primarily because it is essential that he have a higher education and training in order to provide the answers required by physicians and pharmacists. The large majority of detail men have university degrees. There is a definite shortage of graduate pharmacists for detailing. While a company may prefer pharmacists for this role, they are not always available. Consequently, the company may have to take someone with a non-pharmaceutical background."

(Association brief, p. 65;
Hearing, p. 1956)

In answer to a question, Mr. S.N. Conder, General Manager of the C.Ph.M.A., stated that two-thirds of detail men had university degrees:

"THE CHAIRMAN: I suppose you haven't any figures as to the proportion that are fully trained pharmacists or that are trained graduates in medicine or have some other years of training in the same area.

MR. CONDER: Detail men in Canada will not be graduates in medicine at the doctorate level, detail men.

THE CHAIRMAN: They won't be.

MR. CONDER: They wouldn't be as a rule. There undoubtedly have been exceptions to this in the past because, I believe, it is the practice in some European countries, but in this case we had a survey made some time ago -- unfortunately I don't have the figures here with me. It applies to the ratio of detail men holding degrees such as

Bachelor of Pharmacy, Bachelor of Science or possibly pre-med education and other degrees of that level, it is about 8 to 12. The ratio would be 8 to 12. Eight with pharmacy or science as against 12 for the total.

THE CHAIRMAN: Two-thirds of them would have degrees in science or some pre-med or equivalent training; is that it?

MR. CONDER: Yes, they would be primarily pharmacists if you held one figure above the other. It would be primarily Bachelor of Science or its equivalent depending on the university granting the degree."

(Hearing, pp. 1956-57)

Although the usefulness of well-qualified and well-informed detail men to the medical profession was referred to by practising physicians who appeared before the Commission, this view was modified with respect to those representatives of drug manufacturers who were more interested in promoting the use of their companies' products than in providing objective information. Such criticism was dealt with as follows in the brief of the Canadian Pharmaceutical Manufacturers Association:

"Criticisms have been levelled before this Commission with the connotation that companies and their detail men attempt to hide or minimize contraindications. This is incorrect, as will be shown in this sampling of literature containing specific references to contraindications, which we wish to leave with the Commission for later study. [1]

As might be expected, all detail men are not perfect. Their abilities in detailing depend upon their individual capabilities, as it is in any field of endeavour. But it is safe to say that the great majority are well-trained, intelligent individuals who provide a tangible service to the medical profession. This is indicated by the fact that surveys show the doctor considers the detail man to be his front line of information."

(Association brief, p. 66;
Hearing, pp. 1958-60)

[1] This material was filed as Exhibit T-8.

Mr. Conder, General Manager of the C.Ph.M.A., gave the following additional evidence:

"THE CHAIRMAN: We have had the criticism directed that detail men are salesmen and that as salesmen they are concerned about making sales and that is their most important interest and in some cases they may have reason to play down or not play up the possible drawbacks or dangers in the use of a particular drug that they are bringing to the attention of the doctor. I think that is what it amounted to.

MR. CONDER: Yes sir.

THE CHAIRMAN: Some of the criticism went further than you would think justified.

MR. CONDER: As Mr. Thompson of Cyanamid mentioned very briefly in his presentation to you on opening day his company recalled -- he mentioned small cards which he left with you, and the detail man passed the card, and there is further information such as the 20-page brochure I mentioned earlier which is available to doctors. . . . It definitely shows contraindications. We have filed samplings of literature. This material is either sent to the doctor when he writes in to the company for information, or in some cases it may actually be a small explanatory card which goes into the doctor's file and may be attached to the piece of direct mailing when the direct mail goes out, but the detail men carry them with them so he gives it to the doctor when the doctor asks him about the product which he has possibly read about from brief mention in a medical journal. The detail men will invariably leave the information with him. This is the method in which this particular material is brought to the attention of the profession."

(Hearing, pp. 1959-60)

Pharmacists and doctors visited by detail men may well be the best judges of the quality of the services rendered by such representatives. On this point the brief of The Canadian Pharmaceutical Association, Inc. expressed the following opinion:

" . . . Direct contact, through the activities of field forces of company representatives guided by the company's medical executives and sales managers, provides an opportunity for discussion of matters not always appreciated from the reading of technical papers, amidst the routine of a busy day. Without a doubt, the medical detail man is most familiar with the product of his own company and he emphasizes his company's name and its brand names, but at the same time, he probably conveys information which is available in no other practical form. . . ."

(Association brief, p. 36;
Hearing, p. 2365)

Professor J.L. Summers, Director of Pharmaceutical Services at the University Hospital in Saskatoon, Saskatchewan, who appeared on behalf of the Canadian Society of Hospital Pharmacists testified as follows as to the usefulness of detail men to hospital pharmacists:

"MR. MacLEOD: . . . I was wondering if you could express any opinion as to whether you call upon the services of the manufacturer to as great an extent as the retailer, that is the detail men's knowledge and so on?

PROF. SUMMERS: The detail men do call on us and through us make appointments with doctors on our medical staff who have offices in the hospital. They acquaint us with new products that come out as they come out. I would say perhaps we use their services as much or even a little more than the retail pharmacist does because of the greater scope of pharmaceuticals carried in the hospital. We depend on them.

MR. MacLEOD: What I am trying to get your opinion on is, it has been suggested or it is inferred or some suggestions have been made the manufacturer can sell more cheaply to the hospital, sell at lower prices to the hospital because the hospital doesn't draw on the services to the same extent as the retailer does?

PROF. SUMMERS: I wouldn't agree with that, I think he draws on the services to a much higher degree."

(Hearing, pp. 2282-83)

Evidence as to the quality of the services rendered to them by detail men was received from six medical doctors:

(a) Dr. Nathan Schechter, practising physician and Chairman of the Pharmacy Committee of the Ottawa Civic Hospital:

"MR. MacLEOD: Is their job to sell you drugs or to sell you on the merits of drugs?

DR. SCHECTER: They come around to talk of the various products that their companies make and answer any questions about some of their products, if they have any. They try to promote the sale of their company's products.

MR. MacLEOD: Are there a large number of these coming around? Do they encroach on your time or anything like that?

DR. SCHECTER: Yes, we have visits every week from detail men.

MR. MacLEOD: Are you able to see the detail men every time they call?

DR. SCHECTER: Not every time, no, and we can only give them a brief period of time. And the same applies there: there are some detail men [who] are much better informed about their products than others and have some vital information and answers, or they will get them.

MR. MacLEOD: There are certain detail men who perform a real service for you?

DR. SCHECTER: Yes.

MR. MacLEOD: And I presume those are the ones you will receive if you are pressed for time?

DR. SCHECTER: Yes.

THE CHAIRMAN: Do you know, doctor, whether most of the detail men who are engaged in this field have some pharmaceutical or medical training background, or are they more generally described as salesmen?

DR. SCHECTER: I think a good many of them have had some pharmacological training, but certainly there are some who have not had any pharmacological training; they are salesmen, selling some other products in the same sort of way.

THE CHAIRMAN: I think one of your previous answers indicated that they were not trying to sell the drug but to give you the idea that their product is the best one to prescribe.

DR. SCHECTER: Yes. I think one day last week a detail man came in and showed a graph where their anti-biotic was supposed to be the best, and the next day another one came in and showed a graph where their antibiotic was the best. That is number one."

(Hearing, pp. 252-54)

"MR. BUCHANAN: . . . It occurred to me when you were talking about detail men, the number that come to see you - would you care to make a statement as to whether or not you feel that detail men generally, or representatives as we call them might be taken off the road, as we say, and the companies would be far better to, perhaps, promote their products in another way?

DR. SCHECTER: As I said we welcome some of the detail men because they do discuss some of the newer products very intelligently and are helpful. I think they serve a definite purpose, but we do find there are too many."

(Hearing, pp. 268-69)

(b) Dr. C.H. Reardon, practising physician and Member of the Legislative Assembly of the Province of Nova Scotia:

"MR. MacLEOD: Perhaps you will tell us something about that, the work of the detail men and the literature which they send to you?

DR. REARDON: Well, I think it is common knowledge to the Commission who have been hearing all across Canada of the detail men who visit the Doctor and do outline in detail the new drugs of that particular company. I consider this is a very valuable source of information.

There has been some suggestion from reading through the material here in this green book that the detail men are trying to press the doctors the advantages of their drugs ahead of anybody else. I don't think in my experience that has been done. I find that the detail men are not the aggressive group of drug salesmen that you get the impression they are by reading the paper. They are a group of men, I find, that try to disseminate the information they have which might not be -- I think that it is of benefit to the doctors and to the benefit of their patients that these detail men do come through and give information as they are doing.

MR. MacLEOD: Do you think some detail men are more qualified than others and are more useful to you?

DR. REARDON: Well, I suppose that statement would apply to anybody in the professions, whether lawyer, doctor or whatever he is. There is always some more qualified than others. The same would apply to detail men.

MR. MacLEOD: A doctor testifying in Ottawa gave evidence something to this effect, he found some detail men particularly well qualified and he always made it a point of seeing these men because they had something to contribute to him and certainly other detail men he didn't consider made any contribution at all. He rather sloughed them off.

DR. REARDON: I see them all and they all have something to contribute. I might agree more with one than the other. I think you have to discriminate, decide you agree with them, whether they have anything of value. I don't believe in the fifteen, sixteen years I have been practising I have bumped into any detail men who didn't do some good and didn't give some information that was of some help to me and my patients.

MR. MacLEOD: Your experience, then, is that detail men do give you valuable information?

DR. REARDON: Yes."

(Hearing, pp. 368-370)

(c) Dr. J.W. Reid, practising physician in the City of
Halifax:

"MR. CARIGNAN: Dr. Reid, would you say that the detail men who come visiting have been providing you with useful information?

DR. REID: Well, yes, as a matter of fact the detail man -- here again now is an interesting development in this business because in the early years there weren't so very many of these fellows, and they called on us and we talked about drugs and preparations and so on and we had some time to spend with them.

Gradually the number of detail men increased to the point where it was becoming a problem in the doctor's office, you see, to interview so many and some of us have had to arrange for these interviews by appointment; that is, we have certain hours in which we interview these chaps from the drug houses.

I have found on occasion that these fellows have been extremely helpful, not only in providing me with information concerning drugs, but quite helpful in getting original articles and material for me that I could go back to the sources of these preparations and find how it really works.

I think they are a valuable contact with the doctor. So long as it doesn't become time-consuming I am always glad to see them. In later years the detail men have been seeing more doctors in the hospitals than they have in offices, perhaps. That is one of the changes that has come about in the method."

(Hearing, pp. 398-99)

(d) Dr. J.P. Gemmell, Associate Professor of Medicine at the University of Manitoba:

"DR. GEMMELL: There is one other thing that you are aware of, type of advertising, and this is the direct detailing, detail men employed by pharmaceutical firms who in certain cases but not all are trained pharmacists, and they come to the doctor to explain new products to him to promote his use of the product of his company. This is direct person to person advertising. I think it is fair to say that he certainly can use up a considerable percentage of a busy doctor's time unless he is careful; and I think in his defence in some ways, particularly to the isolated rural practitioner, he represents a professional contact which in many cases is a welcome relief, and I think this must be admitted. Whether this is the correct type of

professional contact for the isolated doctor is hard to say. But I say again, as my father was a rural practitioner, and I have met many of them as a boy with my father, and I still know them. So it does represent this.

THE CHAIRMAN: Do you mean by that, Doctor, that the detail men perform a very useful function in connection with the practices of rural practitioners.

DR. GEMMELL: I don't know whether it is useful but it is certainly - it may be of interest to him. He can talk about things, about medicine with the detail man who is usually well-versed in what has happened to some other doctor that he knows and how so-and-so is doing - professional gossip. I think professional gossip is part and parcel of every professional man or any businessman's life.

THE CHAIRMAN: I am trying to get at: what is the value of the information that the detail man gives to the doctor? Is it more useful to the country practitioner than it would be to the practitioner in a larger centre where he is in contact with other members of the profession all the time? To what extent is it useful?

DR. GEMMELL: I would say this, first of all: their job is to promote the use of their particular company's products but failing that many of them, particularly the ones that are trained men - that are not trained just as salesmen - I think you can see the advertisements for them, Grade 12 education on so on, these people if they are trained pharmacists - some of them are, can give very factual information about the toxic effects of these drugs. . . ."

(Hearing, pp. 511-14)

(e) Dr. Nickerson, Professor and Head of the Department of Pharmacology and Therapeutics at the University of Manitoba:

" . . . in my opinion, whether they have a pharmacy degree or not, the detail man is not a proper man to be detailing the physician, and if he has pharmacy training, one of the specific conditions, I think, of ethical pharmacy is that they should not prescribe, they should recognize they are not in a position to determine what drug the patient should take, and consequently I think it really makes very little difference, perhaps some but not a major difference, whether the detail man is a pharmacist or not. It seems to me, in my experience, and I have had a good deal, it is what he has been told at the sales conference, kicking off a campaign on a new drug or reactivating an old one."

(Hearing, p. 554)

(f) Dr. F.B. Rodman, Assistant Clinical Professor of Therapeutics at the University of Alberta:

"MR. MacLEOD: Touching on the point you just raised, what is your experience with the detail men, or the medical representative? Do you find that they give you valuable information?

DR. RODMAN: Well, their kind, you take 50% of it and throw the rest away, and the 50% that you take you sit and wait to see what comes up.

MR. MacLEOD: Do you find that there are so many of these people that they are a nuisance, and impinge on your time?

DR. RODMAN: No, they are very respectable and courteous people. Many of them are very helpful in a new preparation. If there is a defect that shows up they are very honest and tell me when it comes. It is true that there are a few that you might wish didn't come, but they are a very carefully selected group. I think probably their biggest fault is that they are so enthusiastic about their preparation, and they must be, or they wouldn't be of any value to their firm."

(Hearing, pp. 906-07)

6. Sponsorship of Educational Activities by Drug Manufacturers

In Chapter V, reference was made to the fact that drug companies either directly or through contributions to foundations and similar institutions give support to various research and educational programmes. In some cases the programme is concerned with the company's products but in other cases no direct relationship is maintained. Dr. J.P. Gemmell, of the University of Manitoba, made the following comments on such activities:

"DR. GEMMELL: . . . This is, I think, perhaps a more acceptable form of advertising. One of the ways in which this - you can call it advertising or public service, if you wish, that the pharmaceutical industry or component parts of it do is by means of research, fellowships and student aids and so on. This is not necessarily specific research but this is to give help to promising young men. Another type which is more closely directed towards the medical profession is primarily educational types.

For example, a drug firm sponsoring a course on a particular disease or diseases, which are primarily for the education of the physician.

The use of closed circuit television and the use of films or the making of films available to doctors.

These, of course, tend to certainly advertise the drugs named but often are not necessarily concerned with the firms' products.

Along this line - I think this is conventional in many industrial practices - they might subsidize such a thing as dinners at meetings or cocktail parties and this type of endeavour.

Again, in the prestige type of advertising, they may put out special books which are really mainly directed - and they are in many forms - these are mainly directed to information. Do you want me to show this to the Commission?

MR. MacLEOD: Yes.

DR. GEMMELL: Some of these - you will find are directed towards a disease but they have some advertising things in it.

Other ones of a similar type are almost devoid of advertising. It is underwritten by a pharmaceutical company and is a report of a conference.

The other type is sometimes a rather different educational matter and this is what is sent out by one pharmaceutical firm about the Kefauver Committee of which you may be aware.

. . .

THE CHAIRMAN: Doctor, you might identify these so we will not be confused when we start to read them over.

You have in the last moment or two handed us three volumes. One is entitled 'Metabolic Effect of Adrenalin Hormones' edited by Dr. Churchill and it is published by Ciba Foundation Study Group, No. 6.

This is one of the types of books that you believe are mainly informational rather than simply seeking publicity.

DR. GEMMELL: That is right.

THE CHAIRMAN: The second one is a pamphlet entitled 'Patterns of Disease' published by Drug Publications [sic, Parke, Davis & Company, Ltd.] and it is described as 'Services for the Exclusive Use of the Medical Profession'. That is a similar type of publication?

DR. GEMMELL: That is right.

THE CHAIRMAN: Informational for the medical profession?

DR. GEMMELL: Yes.

THE CHAIRMAN: This particular volume to which we have just referred is entitled 'Special Report on Obesity'?

DR. GEMMELL: That is right.

THE CHAIRMAN: The third one which you have handed to us is entitled 'Statements presented to the Kefauver Committee about Steroid Hormones' by Nobel Laureates, Dr. Edward C. Kendall, Dr. Philip S. Hench, and Merck officials, John T. Connor and Dr. Augustus Gibson.

DR. GEMMELL: This is rather of a different nature.

THE CHAIRMAN: It is similar in this sense; it is mainly informational for use of the medical profession?

DR. GEMMELL: Yes.

THE CHAIRMAN: Rather than what you would ordinarily call publicity directed to advertising?

DR. GEMMELL: Yes."

(Hearing, pp. 493-96)

Activities of this type were also described in the brief of Nordic Biochemicals Ltd.:

"... While we are very loath to spend our limited resources for non-productive promotional purposes, our company has not hesitated to undertake useful and original promotional and educational campaigns. As an example, we may point to the symposium on ACTH which we sponsored jointly with the Hospital St. Francois d'Assise in Quebec City, in 1955. We had become aware at that time that the French language medical literature on ACTH was relatively incomplete, compared to the information available in English. Therefore, we organized a day-long symposium for the benefit of the French speaking doctors in the Quebec City area. Specialists in the field of rheumatology, pediatrics, allergy and endocrinology were brought from Toronto and Montreal to present the latest and most authoritative clinical experience to general practitioners in the area. These proceedings were subsequently published in the medical journal of Laval University, 'Laval Medical', and were distributed in booklet form to the French speaking members of the Canadian medical profession. Although the expense of this conference and the later publication were perhaps out of proportion to the size of our company, we have enjoyed lasting benefit from the good will engendered by this conference."

(Nordic brief, pp. 7-8;
Hearing, pp. 1392-93)

7. Some Social Drawbacks of Massive Advertising and Promotion

The deterioration of effective communication between the medical profession and the drug manufacturing industry, the conveyance of incomplete or misleading information to doctors and the over-use of drugs by the public were attributed to massive advertising and promotional campaigns, in some evidence before the Commission.

The deterioration in communication between the doctor and the manufacturer was described as follows in the brief of Nordic Biochemicals Ltd.:

"... At the same time, the flamboyant overuse of such sales methods has led to increasing coolness between responsible sections of the medical profession and the pharmaceutical industry as a whole. As a consequence, the channels of communication between the doctor and the drug manufacturer deteriorate, and the cost of drug promotion increases. More and more mail is needed to put across

a given idea, more and more time is wasted by detail men in attempting to see doctors who are determined to see as few of these salesmen as possible, and more and more samples are shovelled out in an attempt to catch the eye of the men who write prescriptions."

(Nordic brief, p. 15;
Hearing, pp. 1404-05)

Regarding the dissemination of incomplete or misleading information to doctors, a comprehensive statement is contained in the article "Doctors, Drugs and Drug Promotion" by Dr. Mark Nickerson and Dr. J.P. Gemmell⁽¹⁾. The latter also testified as follows:

"MR. MacLEOD: You have described for the Commission this morning some of the deficiencies of certain of the drug advertising at least. Do you think that this poses a real danger in advertising material circulating to doctors which is inaccurate or misleading? Do you think it poses a danger?

DR. GEMMELL: Well, I think it produces danger. I think I would like to try in my own mind to keep some balance in this. I doubt very much that it is more dangerous than promotion of consumption of tobacco and alcohol.

MR. MacLEOD: I was wondering if you thought there was any danger of a doctor prescribing a drug on the basis of information contained in advertising literature that wasn't accurate and, as a result, perhaps damage the patient?

DR. GEMMELL: I think this potential always exists. If you are prescribing from advertising material there is danger always of this."

(Hearing, pp. 532-33)

(1) The Canadian Medical Association Journal, Vol. 80, April 1, 1959, pp. 520-24; reproduced in the Green Book, pp. 285-90.

"MR. MacLEOD: Do you think it is a good idea from a medical point of view for persons with perhaps no education suggesting to doctors that they should use certain products rather than certain other products?

DR. GEMMELL: This is a difficult question to answer. I would say that I would much prefer not, that they didn't. I would also say that I prefer the doctors to realize the source and motivation behind this type of advertising and judge it accordingly."

(Hearing, pp. 536-37)

With respect to the over-use of drugs by the public, Dr. Gemmell gave the following evidence:

"DR. GEMMELL: . . . I think this: the public are increasingly demanding drugs. I don't think there is any doubt about that.

THE CHAIRMAN: They are demanding more and more drugs.

DR. GEMMELL: Yes, I think when a person comes into a doctor's office he now expects treatment. If I put it this way to you. If one of you gentlemen develop a cold or laryngitis you might call me and say 'I have got to have something for this. I have got to carry on with this Commission'. The correct advice that I would give to you is 'Go to bed and stay in bed. Don't take anything. You will get better'.

The pressure that you would put on me - I have to carry on. I have to be able to talk. I have to carry on with this Commission. My next meeting is in Regina. I have to be there. 'Give me something'. So I will give you some nose drops or I might give you something that will relieve the discomfort of the throat.

I might worry about giving you some penicillin in case you feel sick or get an infection. You might develop a tremendous allergy where there are nose bleeds and the coating of your tongue will slough off. You may be in hospital for a month with a penicillin reaction because you have pressurized me into prescribing for you. I think this is the result of what is continuing; a primitive belief in the magic that occurs with drugs and this magic is drugs now.

THE CHAIRMAN: Has that been accelerated by the appearance of the wonder drugs?

DR. GEMMELL: The very name 'wonder drugs' is the magic. We do not call them excellent drugs, which they are. They are called wonder drugs which means that this brings an element in of the witch doctor.

THE CHAIRMAN: Do I take it from what you have just said there has been an increase in the public belief in the efficacy of drugs because of the development in recent years of very many excellent drugs?

DR. GEMMELL: Yes. I almost feel the public has transferred its belief in doctors to its belief in drugs."

(Hearing, pp. 518-20)

In this respect, Dr. Gemmell's opinion was confirmed by Dr. Mark Nickerson, Professor and Head of the Department of Pharmacology and Therapeutics at the University of Manitoba:

"DR. NICKERSON: . . . Just as an example, I believe that today or in 1960 the total sales of the adrenal steroids, cortisone group, in the United States and Canada was something in the order of \$250,000,000. Now, I must go into the realm of opinion when I say that, that I feel personally I am being very liberal when I say that fifty million of that was needed.

THE CHAIRMAN: 20%, roughly?

DR. NICKERSON: Yes. There are other examples, I think antibiotics are high on the list, where the major percentage is used unnecessarily.

I think that the advertising pressure is a major factor in this, the annual bombardment with the advertising that gives new life to arthritic patients.

Now there is no question, to follow up this example, that in a majority of cases an arthritic who has been having difficulty, if you give him adrenal steroids he will feel much better very quickly. There have been some well-controlled studies in England where they have compared the adrenal steroids with acetylsalicylic acid, showing that after two years the ones on the acetylsalicylic acid were doing just as well as the ones on the adrenal steroids, as far as the overall picture was concerned. I may feel very strong on this point, because my practice is limited to therapeutic problems, and I find today one of the biggest

problems is how to get the patients off the adrenal steroids, because once they have been on them for a year or two you cannot take them off it because their own adrenals are compromised. I think here that the biggest problem - and I don't know that I have an answer to it - is that this pressure has brought about an overall gross over-use of drugs."

(Hearing, pp. 555-56)

CHAPTER XV

CHANNELS OF DISTRIBUTION AND THE STRUCTURE OF DRUG PRICES

1. Marketing Channels

The usual trade channels for the distribution of drugs consist of manufacturers or importers, wholesalers and retail pharmacists. Although in some cases the user of drugs may obtain them from a medical doctor or clinic such purchases are considered to form a very minor part of the general distribution of drugs. The two main channels through which users secure drugs are retail pharmacies and hospitals. The latter usually do not sell drugs to patients but include their cost in the overall daily hospital charge. By proceeding in this way hospitals purchase their drug supplies exempt from sales tax which would be payable if hospitals resold drugs to patients. (1) In addition to government-operated hospitals for which purchases of drugs may be made by government purchasing agencies rather than by the hospital itself, governments may also purchase drugs for special distribution in order to combat or treat specific diseases.

In connection with the survey of the operations in 1960 of pharmaceutical manufacturers made on direction of the Canadian Pharmaceutical Manufacturers Association information was secured on the manner in which 37 of the 40 reporting companies distributed human pharmaceuticals. The schedule furnished to the Commission by the Association (2) gives the following distribution of the ways in which sales were made by the 37 companies:

37 companies sell to wholesalers
36 companies sell to governments
35 companies sell to hospitals
31 companies sell to druggists

(1)

Appendix H to this Report, Excise Tax Act, s.32(1).

(2)

Canadian Pharmaceutical Manufacturers Association,
"Compilation of Results of Special Questionnaire
(dated May 3, 1961) Covering 1960 Figures", Schedule 6.

It is evident from the foregoing that while wholesalers are generally used in the distribution of human pharmaceuticals there is a great deal of direct selling by manufacturers to hospitals, governments and retail druggists. It is pointed out in the Green Book (pp.86-87) that while the druggist can usually buy more advantageously from a manufacturer than from a wholesaler he may be required to place an order of a minimum size or, in any event, his savings may not be appreciable, unless he does place an order of some size. From this the Director concluded that the druggist would tend to buy direct from the manufacturer those drugs which he sells in considerable quantities and to secure from the wholesaler those which he sells in small volume which he requires quickly. The wholesaler thus carries the stock for the retail druggist and many retail druggists rely heavily on this source for supplies.

Some pharmaceutical manufacturers operate branch offices at various points in Canada from which sales may be made to customers.

2. Structure of Prices

As indicated in the previous section most pharmaceutical manufacturers sell to a variety of customers. In some instances the same basis of pricing may be used for all customers, making allowance for the sales tax when the purchases are exempt from such tax. In other instances the price may differ with the class of customer.

The survey of the operations of pharmaceutical manufacturers in 1960, made on behalf of the Canadian Pharmaceutical Manufacturers Association, included an examination of the trade discounts normally allowed to different classes of customers. The discounts are taken from the list prices or suggested resale prices of the manufacturers which may be regarded as the retail list prices. The following compilation of rates of discounts is included in the report of the survey for 1960:

"Normal Trade discounts allowed on sales of human
pharmaceuticals:

37 companies answered the question regarding normal trade discounts and the following is a brief analysis of the replies -

- (i) On sales to hospitals (35 companies of the 37 sell to hospitals)

4 quote 'net' prices

1 allows trade discount of less than 40%

18 allow " " " exactly 40%

12 " " " over 40%, mostly in range of 40 to 50%.

- (ii) On sales to Governments (36 companies) -

15 special prices by quote or tender

2 allow discount of less than 40%

8 allow discount of exactly 40%

11 allow discount of over 40% up to 50%

- (iii) On sales to wholesalers (37 companies) -

3 allow discount of less than 40%

8 allow discount of exactly 40%

25 allow discount of over 40% up to 50%

1 allows discount of over 50%

- (iv) On sales to druggists (31 companies)

24 allow discount of exactly 40%

7 allow discount of over 40% up to 50%

In addition, certain companies indicated that they allowed volume discounts, and special discounts on certain products from time to time." (1)

(1)

Ibid., Schedule 6.

It will be noted from the foregoing compilation that 25 of the 37 companies which reported allow wholesalers discounts over 40 per cent and up to 50 per cent. This basis of pricing conforms to that indicated in the Green Book as probably being the most common, namely, discounts of 40 per cent and 16 2/3 per cent on sales to wholesalers. Information gathered by the Director further indicated that when such discounts were allowed, the wholesaler usually passes on the 40 per cent to the retailer or to the hospital. The latter will also be relieved of sales tax (Green Book, pp.86-87). At the same time the above compilation shows and the Green Book also points out that pricing policies of different manufacturers vary and while a majority may have a similar pattern of discounts this is not standard throughout the industry.

The Green Book (p.84, p.88) states that information obtained by the Director indicated that a number of small manufacturers allow a discount of 50 per cent off list or suggested resale prices and that frequently such firms allow this rate of discount to all customers - wholesalers, retail druggists, hospitals (and less sales tax), doctors, clinics, institutions, etc. Most of the larger firms, the Director found, allow doctors only 25 per cent off list. One exception is Cyanamid of Canada Limited which allows doctors a 40 per cent discount but does not give any additional discount to wholesalers. Mr. R. B. Thompson explained the company's policy to the Commission as follows:

"MR. THOMPSON: . . . We operate our own distribution facilities in Canada, and sell from six locations in the country. Although at one time additional discount was allowed to wholesalers, we came to the conclusion that we could do business with good efficiency and more economically by selling direct, and therefore we have not encouraged distributors through an extra discount.

THE CHAIRMAN: All your customers are commercial customers? Wholesalers or retailers, regardless of size or volume of purchase, get the same price?

MR. THOMPSON: On antibiotics, yes. There is one qualification that will have to be made. We do have an incentive which we call the Lederle Purchase Plan, and under this plan a pharmacist, for example, can earn an additional discount depending on the total size of the order. This discount does not apply in general to the prescription drugs.

He is unable in effect to influence the sale. He merely acts as the professional dispenser, but we have other preparations in our line, notably vitamin products, where the pharmacist can encourage sale considerably by displaying packages in his store, and by recommending a product to a customer, and those products generally are the subject of the additional discount which increases with the size of the order. This is not true, however, of the antibiotics. It is not true of Aristocort.

THE CHAIRMAN: Tranquilizers?

MR. THOMPSON: That is correct. We are introducing a new tranquilizer under the trade name of Trepidone at the present time, and this is a prescription item, and the purchase plan discount does not apply.

THE CHAIRMAN: It does not apply to the prescription item?

MR. THOMPSON: No."

(Hearing, pp.1616-17)

Later in his evidence Mr. Thompson said that a physician could order from one of the depots operated by Cyanamid at the same price as that charged a retail druggist (Hearing, p.1819). An opposite policy is followed by Eli Lilly and Company (Canada) Limited which, the Commission was informed, sells only to wholesalers. Retail druggists and hospitals desiring products of Eli Lilly and Company (Canada) Limited must place their orders with wholesalers as the company does not sell directly to them.

The discussion so far has been concerned primarily with prescription drugs. The Director found that with respect to proprietary drugs, household remedies and sundry drug products, the pattern of discounts varied widely but that discounts of less than 40 per cent seemed to be usual. (However, two retail pharmacists informed the Commission that the terms on which they purchased proprietary drugs were similar to those applying on the purchase of ethical drugs). In addition, at certain times of the year and for certain products manufacturers may offer "deals" involving special discounts or free goods with orders of specified size. Quantity discounts may also be allowed. Such discounts, as indicated above in the case of Cyanamid of Canada, are not normally allowed on prescription drugs (Green Book, p.87).

One of the large drug wholesalers in Ontario is Drug Trading Company Limited, which is a co-operative owned by retail druggists. The co-operative company grants rebates to its members (over and above regular discounts) and the Director found that other wholesalers in Ontario have adopted a similar practice in order to remain competitive (Green Book, p.87).

CHAPTER XVI

PURCHASES OF DRUGS BY HOSPITALS

1. Factors Affecting Relative Prices of Drugs to Retail Druggists and Hospitals

At the hearings held by the Commission considerable evidence was given as to prices paid by hospitals for ethical drugs and the Green Book also examines this matter in some detail. As has already been mentioned on several occasions, purchases of drugs by hospitals are normally exempt from sales tax, so that there is a difference arising from this factor between the price paid by a retail druggist and that paid by a hospital when both are sold on the same discount basis. As the tax is normally levied on the manufacturer's price to the wholesale trade, the difference approximates 8.3 per cent of the price paid by the druggist which is equivalent to 11 per cent on the basis used for the tax.

In addition to the difference arising from the sales tax the Director found that there were several other factors which lead to differences in the prices paid by hospitals and by retail druggists. These may be summarized as follows:

1. Hospitals may be charged special prices by manufacturers which are lower than 40 per cent off list.
2. Prices may be offered for purchases in large quantities which are appropriate for hospital purchases but may be too large for a retail druggist to stock.
3. Hospitals may buy larger unit packages (such as one thousand or five thousand tablets) whereas the retail druggist would buy packages of twenty-five or fifty tablets which are proportionately more expensive.
4. In the case of some drugs, the dosage forms sold by the retailer are less commonly used, produced in smaller quantities and more expensive to manufacture than the standard dosage form generally used in hospitals (Green Book, pp.85-86).

Other points of difference were given by The Canadian Pharmaceutical Association, Inc.:

- "(1) The lower number of demands made upon a hospital pharmacy for a variety of drugs and preparations thereof, such as is experienced by the community pharmacist who serves a great variety of individual physicians in his area.
- (2) A hospital usually has larger sums of money available to invest in larger quantities and has a budget which permits extensive pre-use purchasing.
- (3) Hospital purchases are often made by tender.
- (4) A formulary system enables the hospital pharmacy to reduce its number of brands (or non-brands) and dosage forms.
- (5) Greater storage facilities in hospitals.
- (6) 'Free goods' often available to hospitals with the purchase of large orders or special contracts. The amount of free drugs available for clinical investigation is said to be not great, but it must have an ultimate effect on overall drug utilization. "

(Association brief, pp.46-47; Hearing, pp.2412-13)

The compilation of trade discounts made in the survey for the Canadian Pharmaceutical Manufacturers Association, which was presented in Chapter XV, gives some statistical indication of the different price levels. A reference to that compilation shows that 4 manufacturers out of 35 quoted "net price" to hospitals, 18 allowed 40 per cent discount and 12 allowed discounts of more than 40 per cent.

2. Purchase of Drugs on Tenders

Evidence given to the Commission indicates that when the quantities involved are of sufficient size and alternative sources of supply are available the practice of calling for tenders for the supply of drugs for use in hospitals is growing. In a number of instances cited to the Commission the practice resulted in a substantial reduction in prices from those normally offered on hospital

purchases. Evidence was also given that for some drugs quotations on tenders did not differ greatly from prices usually available. Professor J. L. Summers, Director of Pharmaceutical Services of the University Hospital in Saskatoon and Associate Professor of Pharmacy at the University of Saskatchewan was asked by Mr. J. J. Frawley, Q. C., counsel for the Province of Alberta, about the practice of the University Hospital in inviting tenders for the supply of drugs:

"MR. FRAWLEY: Hospitals such as yours ask for bids for its drug supplies?

PROF. SUMMERS: For some of its drugs; for a very limited number of its drugs.

MR. FRAWLEY: Then the practice of calling for tenders is not a general practice? It is the exception?

PROF. SUMMERS: This calling for tenders on drugs, where it is convenient to do so, yes. Now, you must realize, Mr. Frawley, it would be a bit ridiculous to call for tenders on 50 capsules or tablets, but in order for tendering to be effective, one must buy in quantities exceeding one thousand dosage units of any given drug, even though it may not be -- if you are thinking of dollar volume wise I would suggest, yes, the majority are tendered. If, on the other hand, you are speaking about individual drugs, I would say certainly not because the number of drugs which I buy on tender would be less than 20.

MR. FRAWLEY: Let's take it with respect to the three large groups with which this Commission seems to have been most concerned. I am referring to the antibiotics, the corticosteroids and the ataractics or tranquilizers.

PROF. SUMMERS: You can't take a group. Let's take specific drugs within the group, because even within these groups there are specific drugs which are supplied by only one individual manufacturer."

(Hearing, pp.2235-36)

Professor Summers further testified that tenders were invited only from suppliers in whom confidence was placed so that the firm submitting the lowest bid was automatically successful (Hearing, p.2240). He gave the following evidence as to the general level of prices on tenders:

"THE CHAIRMAN: One further question appeared to me, Mr. Summers. You mentioned when you called for tenders you got a variety of tender prices?

PROF. SUMMERS: That is right.

THE CHAIRMAN: Is it common that there is quite a wide variation in the tender price?

PROF. SUMMERS: No sir. It usually varies only a few cents per 100.

THE CHAIRMAN: Another question arises, and I don't know whether you can answer it. Are you in a position to state whether the tender prices you get when you call for tenders are around the same level or slightly lower or substantially lower than the prices you would get if you called for the same product from the companies without the tender?

PROF. SUMMERS: I am sorry I cannot make a general statement on this because some of the drugs which we purchase on tender or contract, are drugs which are not used outside hospitals, and therefore they are very specific.

In some cases there is a fairly wide variation between the tender price and what it would normally cost the retail pharmacist to buy. In other cases, the difference is but a few cents, and in some cases there is no difference other than that of subtracting the sales tax.

THE CHAIRMAN: Have you had any experience in buying a drug without calling for tenders, and then on another occasion calling for tenders on the same drug?

PROF. SUMMERS: Yes sir.

THE CHAIRMAN: And have you observed any variation in the price?

PROF. SUMMERS: Yes sir, not always.

THE CHAIRMAN: Is it very substantial?

PROF. SUMMERS: No, I would not say that. I would have to examine our records to be precise. But as a general statement, it is usually not a wide difference, not a great difference.

THE CHAIRMAN: Not a great difference?

Table 17

Prices of Certain Drugs to Retailers, Hospitals
and University Hospital, Edmonton, Alberta

Generic Name	Brand Name and Manufacturer	Price to Retail Pharmacist per 100	Price to Hospital per 100	Tender Price to University Hospital, Edmonton (1) per 100	Bid Price per 100 as percentage of Usual Price to Hospitals
		\$	\$	\$	%
Tetracycline (250 mg.)	Cosa-Tetracyn (Pfizer)	28.70 (2)	19.18 (3)	16.50 (20,000 lot)	86.0
	Tetrex (Bristol)	28.70 (2)	26.33 (4)	14.95 (20,000 lot)	56.8
	Muracine (Nadeau)	19.00 (5)	17.12 (5)	12.50 (6) (\$2.00/16) (20,000 lot)	73.0
	Achromycin (Lederle)	25.88 (7)	23.27 (3)	21.81 (6) (\$3.49/16) (20,000 lot)	93.7
Prednisone (5 mg.)	Meti-corten (Schering)	13.62 (2)	7.00 (8)	1.62	23.1
Triamcinolone (4 mg.)	Aristocort (Lederle)	23.00 (7)	17.27 (3)	16.41	95.0
	Kenacort (Squibb)	23.04 (7)	18.65 (3)	18.65	100.0
Dexamethasone (.75 mg.)	Decadron (Merck)	17.88 (2)	14.50 (3)	11.50	79.3
	Deronil (Schering)	17.88 (2)	14.50 (3)	14.50	100.0
Methylpred-nisolone (4 mg.)	Medrol (Upjohn)	23.01 (2)	(9)	10.73	..

(See footnotes - p. 315)

- (1) See Exhibit T-5.
- (2) Calculated on the basis of the company's discount to this class of trade.
- (3) Special hospital price, tax exempt, actually stated in the particular company's price list.
- (4) Calculated according to the company's usual discounts to retailers and less federal sales tax.
- (5) These prices received directly from the company by telephone.
- (6) Calculated on the assumption that the price for 100 is 100/16 times the price for 16. The price for 16 was the price actually bid.
- (7) Price actually stated in company's price list.
- (8) Schering has special hospital prices for Meticorten of 500 for \$35.00, 1000 for \$57.00, and 5000 for \$260.00. Price shown is one fifth of the price for 500.
- (9) Upjohn's discounts to all classes of trade are 40 per cent except to Government accounts which are handled on an accepted tender basis. The Commission is in doubt as to whether or not federal and provincial hospitals would be considered by Upjohn as government accounts.

PROF. SUMMERS: Not a great difference from the price that the hospital normally would pay.

Do I make myself clear, because as you have stated, there are some drugs which by tradition are sold normally at low prices to the hospital, much lower than the retail pharmacist can obtain them for.

THE CHAIRMAN: Hospitals have certain advantages with regard to sales tax?

PROF. SUMMERS: Yes sir."

(Hearing, pp.2260-62)

Information about purchases of drugs on tenders by the University Hospital in Edmonton was furnished to the Commission by Mr. J. J. Frawley, Q. C., counsel for the Province of Alberta, in Exhibit T-5. The information presented related to purchases of drugs falling in the classes of antibiotics, corticosteroids and tranquillizers. Table 17 gives the prices quoted on tenders as shown in Exhibit T-5, together with the trade prices to retail pharmacists and hospitals. It should be kept in mind that the prices to wholesalers and retail pharmacists include sales tax. From Table 17, it is clear that in some cases (Deronil and Kenacort) nothing was saved by calling tenders. In those cases in which savings were made, they ranged from 5 per cent (Aristocort) to 76.9 per cent (Meticorten).

Mr. K. O. Mackenzie, Deputy Minister of Welfare of the Province of Manitoba, gave evidence that a considerable variation in prices between manufacturing firms for equal quantities of the same type of drug has been found when tenders are called. The brief which he presented included the material condensed in Table 18 and the following comments:

"2. Variations in tenders to Government agencies:

Although as we have shown there is a substantial cost saving in hospital over retail purchasing of drugs, our experience in prices quoted by manufacturers on Provincial Government tenders for drugs has revealed a price variation between manufacturing firms for equal quantities of the same type of drugs of up to 491%. These price discrepancies occurred in a recent tender call for drugs by generic names for use in mental hospitals in the province, the quotations between high and low bidders for drugs were 194%, 221%, 279%, and 491%."

(Government of Manitoba brief, p.8; Hearing, p.579)

Table 18

Variations in Price Quotations by Different
Manufacturing Firms for the Same
Quantities of the Same Drugs

<u>Drug</u>	<u>Company</u> ⁽¹⁾	<u>Price Quoted</u>	<u>Per cent difference between highest and lowest prices quoted</u>
	1	\$140)	
)	
	2	154)	
)	
	3	204)	
)	
	4	208)	491%
)	
	5	240)	
)	
	6	320)	
)	
	7	368)	
)	
	8	828)	
)	
	1	220)	
)	
	2	718)	
)	
	3	834)	279%
)	
	1	126)	
)	
	2	295)	221%
)	
	3	360)	
)	
	4	405)	
)	
	1	384)	
)	
	2	1128)	194%
)	
	3	1128)	

The same number does not necessarily refer to the same company (Hearing, p.579).

Source: Brief of Government of Manitoba, p.9.

Appendix B of the brief presented to the Commission on behalf of the Government of Saskatchewan deals with the Government's experience in drug purchasing. It is indicated that, generally speaking, drugs are purchased on a tender basis through the Purchasing Agency where this is feasible. Some examples of savings being made in this way are quoted from Appendix B to the brief:

"(a) Anti-Diabetic Agents

. . .

- (2) Tolbutamide - This was originally available only from companies D and E, who submitted identical bids of \$2.50. Both these companies later reduced the price to \$2.40. Subsequently Company C bid \$1.60. This resulted in a bid of \$2.16 from Company D. The product of Company C is now stocked routinely.

. . .

(c) Cortico Steroids

Comparative bids were experienced in the case of Prednisone, Prednisolone and Triamcinolone. Bids from two different companies for Prednisone 5 mg. tablets were \$2.80 and \$1.52 $\frac{1}{2}$. For Prednisolone 5 mg. tablets they were \$14.00 and \$5.70. For Triamcinolone, they were \$7.85 and \$9.33 for the 2 mg. tablet and \$15.70 and \$17.27 for the 4 mg. tablet.

(d) Vitamin Supplements

After agreement was reached with the doctors using these preparations, competitive bidding was sought and a product for which \$1.10 had been paid was obtained for 50¢."

(Appendix B to the Government of Saskatchewan
brief, pp.1-2; Hearing, pp.775-77)

Mr. Wilfred Totten, Administrative Pharmacist, Department of Public Health, Province of Saskatchewan, testified that when tenders are called varying prices may be received from the firms making bids. However, he went on to say that while the department's experience had been limited he had not found the same firms were the low bidders for different products (Hearing, pp.786-87).

Dr. J. D. Ross, Minister of Health, Province of Alberta, cited to the Commission the results which had been obtained in setting up specifications for 440,000-unit tablets of penicillin which had a retail price of 20 to 25 cents per tablet. In 1959, the first year in which tenders were called for 60,000 tablets, the low bid was \$5.40 per 100 tablets or 5.4 cents per tablet. On a subsequent tender for a quantity of 130,000 tablets, the price was reduced to \$4.75 per 100 tablets. In 1960, a tender of \$3.42 per 100 tablets was received and in 1960-61, when bids were invited for 192,500 tablets, a price of \$2.95 per 100 tablets was quoted by two firms (Hearing, pp.887-88).

The evidence received by the Commission in regard to purchases of drugs by governmental agencies and hospitals indicates that for some products manufacturers offer special prices which are substantially lower than the usual trade prices. A number of examples of such pricing will be found in the Green Book. The evidence also shows that when drugs are required in substantial quantities and when alternative sources of supply are available significant savings are likely to be made when purchases are made through the tender system. The evidence suggests that the practice of calling for tenders when this method of purchasing is feasible is becoming more widespread.

CHAPTER XVII

CHANGES IN MANUFACTURERS' LIST PRICES SUBSEQUENT TO SURVEY MADE BY DIRECTOR

1. Information Obtained by the Commission

In order to secure information on prices more recent than that contained in the Green Book, the Commission requested manufacturers who had submitted returns to the Director to furnish copies of their current price lists in 1961. The price lists sent to the Commission in response to this request were received during the period May - July, 1961. In addition, the following material obtained by the Commission contains information on the prices of drugs:

Exhibit T-3 - Gilbert Surgical News, May, 1961 (issued by
Gilbert & Co., Toronto)

Exhibit T-5 - "Statement Showing Drug Prices in Alberta -
Antibiotics, Corticosteroids, Tranquillizers"

Exhibit T-17 - Price Book of Drug Store Merchandise (May, 1961)
published by the Canadian Pharmaceutical Journal

Canadian Pharmaceutical Journal, issues of January, March and
April, 1962

Drug Merchandising, November 1961 .

Among the firms whose prices are presented in the Green Book is Gilbert & Co. of Toronto, which relies to a considerable extent on imported drug supplies and distributes its products under generic names. The Commission has found that in some cases the Gilbert prices quoted in the Green Book do not reflect the actual discounts which the firm was allowing to retail druggists and hospitals in 1959 or, in a few instances, show the list prices then in effect. According to information received by the Commission the usual discount from list prices which Gilbert granted in 1959 were 50 per cent off list to doctors and 60 per cent off list to druggists, with a similar discount to hospitals. Revisions of the prices of Gilbert products given in the Green Book have been made by the Commission on the basis of this discount structure, and are shown in Table 19 in comparison with the former with a reference to the page in the Green Book where such prices appear.

Table 19

Prices of Gilbert & Co.

<u>Item</u>	<u>Quantity</u>	<u>List Price</u> \$	<u>Price to Retailer</u> \$	<u>Price to Hospital</u> \$
<u>penicillin (vials - 10 cc., 300,000 I.U. per cc., for aqueous suspension)</u>				
Green Book, p.161		2.00	1.00	.90
Revised on basis of 60% discount		1.60	.64	.64
<u>pen-V Potassium tablets, 500,000 I.U.</u>				
Green Book, p.166	100's	-	20.00	18.00
Revised on basis of 60% discount	100's	40.00	16.00	16.00
<u>chloramphenicol, 250 mg. capsules</u>				
Green Book, p.174	100's	40.00	18.00	16.20
Revised on basis of 60% discount	100's	40.00	16.00	16.00
<u>xytetracycline, 250 mg. capsules</u>				
Green Book, p.174	100's	56.00	26.00	23.40
Revised on basis of 60% discount	100's	56.00	22.40	22.40
<u>tetracycline, 250 mg. capsules</u>				
Green Book, p.174	100's	52.00	24.00	21.60
Revised on basis of 60% discount	100's	52.00	20.80	20.80
<u>chlorpromazine, 25 mg. tablets</u>				
Green Book, p.188	100's	-	2.50	2.25
Revised on basis of 60% discount	100's	5.00	2.00	2.00
Green Book, p.188	1000's	45.00	22.00	19.80
Revised on basis of 60% discount	1000's	44.00	17.60	17.60
<u>50 mg. tablets</u>				
Green Book, p.188	100's	-	4.50	4.05
Revised on basis of 60% discount	100's	9.00	3.60	3.60
Green Book, p.188	1000's	82.00	38.00	34.20
Revised on basis of 60% discount	1000's	76.00	30.40	30.40
<u>100 mg. tablets</u>				
Green Book, p.188	100's	-	8.00	7.20
Revised on basis of 60% discount	100's	16.00	6.40	6.40
Green Book, p.188	1000's	120.00	75.00	67.50
Revised on basis of 60% discount	1000's	150.00	60.00	60.00

Table 19 (cont'd)

Prices of Gilbert & Co.

<u>Item</u>	<u>Quantity</u>	<u>List Price</u> \$	<u>Price to Retailer</u> \$	<u>Price to Hospital</u> \$
<u>Meprobamate, 400 mg. tablets</u>				
Green Book, p.193	100's	-	2.25	-
Revised on basis of 60% discount	100's	4.50	1.80	1.80
Green Book, p.193	1000's	-	17.50	-
Revised on basis of 60% discount	1000's	35.00	14.00	14.00
<u>Reserpine, 0.25 mg. tablets</u>				
Green Book, p.200	1000's	15.00	-	3.75
Revised on basis of 60% discount	1000's	15.00	6.00	6.00

Sources: Gilbert Surgical News, November 1959 (issued by Gilbert & Company, Toronto)
Drug Catalogue, 1959, Jules R. Gilbert Ltd. (issued by Gilbert & Company, Toronto)

2. Information Presented in the Green Book

In Chapter XV of the Green Book the Director has presented information on the elements of costs which arise in the manufacture of prepared dosage forms of drugs. The same chapter also gives in considerable detail manufacturers' selling prices of prepared dosage forms of a large number of drugs to retail druggists, to hospitals and to the Federal Government, as well as the list or suggested resale price. Where the information was available particulars are also given of the cost of the basic drug and costs of manufacturing. The drugs for which such information is given in Chapter XV of the Green Book fall largely in the classes of antibiotics and tranquillizers.

The costs in this connection are the direct costs of manufacturing and preparing in dosage form the drugs in question. Such costs do not represent the total expenses of the drug firm which would include expenditures on research and development, costs of distribution and promotion and other expenses beyond the direct cost of manufacture.

The information given in the Green Book on costs and selling prices of particular dosage forms of certain drugs will not be reviewed in detail here, but some examples drawn from that material are given and reference may be made to the Green Book for further particulars.

The Director found that the prices of older penicillins had declined enormously since their introduction. An example is given of penicillin G. procaine, 10 cc., 3,000,000 I.U. which was introduced by Eli Lilly and Company (Canada) Limited with a list price of \$23.40 in 1948 and which had a list price of \$1.50 in September, 1959 (Green Book, p.162). Mark-ups over cost were found by the Director to be relatively low in the case of older penicillins on sales by manufacturers to hospitals and government departments but small tablets in small sizes which would be more commonly bought by consumers on prescription were relatively much more expensive. Costs in prepared dosage form of 100 tablets 500,000 I.U. were reported by manufacturers in 1958 to range from \$2.93 to \$5.56. Prices to retailers in 1959 were \$17.85 to \$18.18 per 100 tablets for two brand name manufacturers and \$10.00 to \$14.46 for two manufacturers selling under generic name. The retail list prices were \$29.76 to \$30.30 for the former and \$24.10 for one of the latter (Green Book, pp.159-60).

Streptomycin and dihydrostreptomycin were the next antibiotics to be discovered after penicillin and, likewise, were highly priced at first but have also experienced a very large decline. Manufacturers reported to the Director that costs of one gram vials of dihydrostreptomycin ranged from 21 cents to 30 cents per vial. Selling prices in 1959 of one brand name manufacturer for this dosage were 41 cents to hospitals, 46 cents to retailers. The retail list price was 77 cents (Green Book, pp.167-68).

New types of penicillin are generally subject to patent rights although supplies of some types are imported by firms not holding licences from the Canadian patent holders. The new types of penicillin include benzathine penicillin G, various types of penicillin V and the synthetic penicillin, phenylethcillin potassium, commonly referred to as penicillin 152. A wide variety of costs for new penicillins was reported to the Director for basic drugs and prepared dosage forms but selling prices were very similar in most cases. In the case of potassium penicillin V, purchase cost of the basic drug was reported as about \$120.00 per kilogram by two firms and as about \$265.00 for a third. A firm which acts as agent for Italian and Danish drug firms reported that it sold potassium penicillin V at prices ranging from \$44.00 to \$73.00 per kilogram f.o.b. Europe in 1959. Examples of costs of prepared dosage forms reported to the Director were the following for a package of 100 tablets or capsules of 200, 000 I. U. or 125 milligrams: penicillin V, \$3.17; potassium penicillin V, \$2.68; and penicillin 152, \$4.68 to \$6.48 plus packaging. Prices to retailers in 1959 for this size of package ranged from \$20.25 to \$20.28 and the retail list prices ranged from \$33.75 to \$33.80 (Green Book, pp.163-65).

Erythromycin, another antibiotic, is sold under brand names by two large drug firms and under generic name by another. One firm reported that it imported erythromycin stearate in basic drug form at a cost of \$160 per kilogram. Two firms reported finished package costs of 24 or 25 tablets of 250 milligrams at \$1.25 to \$1.28 per package. Selling prices to druggists were \$8.40 to \$8.85 and the retail list prices ranged from \$14.00 to \$14.75 (Green Book, p.177).

In the case of most of the tranquillizing drugs referred to in the Green Book, information is given as to the cost of basic drugs to firms in Canada, but details are not usually given of the cost of producing and packaging prepared dosage forms. In general, the Director found that the cost of preparing tablets or capsules formed a small part of total cost but that costs of packaging and labelling are relatively more expensive for small packages than for larger ones. One example given in the Green Book showed packaging costs of almost 10 cents per package for 50 tablets, a little over 16 cents for packages of 500's and about 42 cents for packages of 5, 000's (Green Book, pp.153-54).

Some illustrations are given in the Green Book of the cost of the theoretical amount of a bulk drug required to prepare a particular dosage form in relation to the cost of the basic drug. It is pointed out that the quantities used as the basis for such calculations are theoretical because they do not allow for wastage, the necessity of using extra quantities of the drug to ensure that each dose will be of at least minimum specifications, and similar factors (Green Book, p.152).

The tranquillizing drug, chlormezanone, is sold by Winthrop under the brand name, Trancopal. Imports of the drug are made by Winthrop from its American parent company in bulk quantities of tablets which are packaged for resale in Canada. Costs of 100 milligram tablets in packages of 100 were reported to the Director to be 51.42 cents per package. The selling price to retailers was \$7.50 and the retail list price was \$12.50 (Green Book, pp.185-86).

Another tranquillizing drug, chlorpromazine, is sold by Poulenc in Canada under the brand name Largactil. Information obtained by the Director indicated Poulenc purchased chlorpromazine hydrochloride for tablets and drops from Fine Chemicals at \$53.00 per kilogram. On this basis the theoretical cost of the drug in Largactil tablets of 25 milligrams would be 13.2 cents per 100. Selling price to retailers was \$6.30 for 100's and the retail list price was \$10.50. Poulenc had a special price of \$21.00 per 1000 for hospitals and other buyers in large quantities (Green Book, pp.186-87).

Gilbert and Empire also reported the distribution of chlorpromazine. Cost of the basic drug was reported by Gilbert at \$41.40 per kilogram in May, 1960 and at \$38.00 by Empire. Presumably both prices would have been f.o.b. Italy and would not include freight, duty and sales tax. Gilbert's prices, as revised, were \$2.00 to retailers for 100's, 25 milligram tablets, with a retail list price of \$5.00. Empire's price to retailers was \$2.20 (Green Book, p.188).

Meprobamate, patent rights for which are held by Carter Products Inc., New York, is sold in Canada by several firms under brand names and by other firms under its generic name. Ayerst's brand, Miltown, and Wyeth's, Equanil, are among those popularly known. Fine Chemicals, which has been licensed to produce the drug in Canada, reported to the Director that its selling price was \$9.00 per kilogram. One custom manufacturer reported that it bought prepared tablets of 400 milligrams in Denmark and resold such tablets in Canada to other drug firms at \$6.25 to \$6.50 per thousand. On the basis of \$9.00 per kilogram the theoretical cost of the basic drug in 400 milligram tablets would be 18 cents for 50 tablets and \$1.80 for 500. Retail list prices of brand name products ranged from \$5.00 to \$6.00 for 50's and from \$45.00 to \$52.50 for 500's. However, the drug under generic name had retail list prices ranging from \$14.00 to \$16.50 for 500's (Green Book, pp.192-93).

The foregoing are only a few of the many examples given in the Green Book in much greater detail. They serve to show, however, the wide variation in the cost of basic drugs and the relationship between basic drug cost, cost of prepared dosage forms and the level of prices to retail druggists and to the general public.

3. Changes in List Prices Since 1959

As already described, the Commission secured price lists of manufacturers which were current in May - July, 1961 and some partial information on later drug prices. In order to simplify the presentation and avoid extending the review to undue length attention will be directed primarily to the list prices reported by manufacturers which indicate the nominal retail price level. If it is assumed that the discounts extended to different classes of customers remain unchanged then any changes in manufacturers' list prices would result in proportionate changes in the prices at which manufacturers sell to retailers and to wholesalers. Reference will be made principally to changes in list prices since 1959 but it should be kept in mind that sales are made by manufacturers at discounts from such prices.

In view of the interest shown in corticosteroids during the hearings held by the Commission, information about changes in the prices of drugs in this class will be presented as well as information relating to the broad classes of antibiotics and tranquillizers which are dealt with extensively in the Green Book.

In referring to the prices of individual companies, use will be made of the abbreviated name of the firm. The full name of each company will be found in the Green Book, Appendix I.

4. Older Penicillins

The Green Book divided penicillins into two classes, "old" and "new". The terms are not used in the sense that the new forms have supplanted the types first introduced because there are differences in their therapeutic qualities and the older penicillins are still the drugs selected in many situations. The Director found that the older penicillins are virtually free of patent control while new penicillins are subject to patents. A number of firms obtain their supplies from parent or affiliated companies outside of Canada, while other firms import from various other sources.

As previously mentioned, prices of older penicillins have been reduced greatly in the period since the end of World War II. An example of the reduction in recent years is contained in the following excerpt from the evidence of Mr. J. W. R. Shaw, Departmental Purchasing Agent, Department of Veterans Affairs:

"Penicillin ammonium, 500,000 units we were purchasing in September, 1956, 100 tablets at \$13.35. In February, 1960 100 tablets were at \$3.95".

In the opinion of the Director, one factor which contributed to the reductions in the prices of older penicillins was the absence of patent control which meant that the drug has been freely available to all firms wishing to deal in it. The importance of the absence of patent control was questioned by several witnesses. Mr. R.B. Thompson of Cyanamid of Canada Limited said that his company had made penicillin by the now obsolete surface fermentation method while competitors converted, with an interruption of production, to the deep fermentation method, with sharply reduced costs of production. Mr. Thompson also said that a large over-capacity for the production of penicillins had developed which led to some producers being forced out of business (Hearing, pp.1700-03).

The brief of the Canadian Pharmaceutical Manufacturers Association referred to the closing down of Merck's plant for the manufacture of penicillin, streptomycin and cortisone at Valleyfield, Quebec and attributed this to imports from low cost countries. However, it was brought out during the appearance of Mr. S. N. Conder, General Manager of the Association, that the chief source of Canadian imports of penicillin and streptomycin has been the United States (see, also, Table 5, Chapter IV). Mr. Conder said he thought that American companies with subsidiaries in Canada might be attempting to meet imports from Europe by manufacturing in the United States (thereby gaining the economies of mass production) and exporting the product to Canada rather than manufacturing here (Hearing, p.2124).

It does not appear to the Commission that the reasons advanced by Mr. Thompson and Mr. Conder for the competitive conditions which have developed in the pricing of the older penicillins can be considered apart from the factor mentioned by the Director, namely the absence of patent control. If the production of the older penicillins had been conducted under extensive patent rights then each new development would have been subject to patent control. This would have limited freedom of entry into the production of these drugs and it would be expected that production facilities would have been closely related to the requirements of the market at established prices. Under extensive patent control there would have been much less opportunity for the creation of excess capacity and the inroads of competitive products which have taken place in the absence of such controls. The Commission, therefore, agrees with the Director that the absence of patent control has contributed to the active competitive conditions in the supply of the older penicillins which have led to the marked reductions in their prices.

The following comments may be made on changes in prices of older penicillins from those set out in the Green Book on the basis of the information on manufacturers' list prices obtained by the Commission.

List prices for June 1961 indicate that for tablets of 500, 000 I. U. penicillin potassium G, Bristol had held its prices at the level of

December 31, 1959 while Ayerst and British Drug Houses had dropped theirs by substantial amounts. In June 1961, Ayerst, British Drug Houses, Frosst and Will had identical list prices for 12's; the first three had identical list prices for 100's; and Ayerst and Frosst had substantially the same prices for 500's. Of these companies, all but British Drug Houses sold by brand name. Bell-Craig and Will had identical prices for 100's, while Empire's price for 100's was 50 cents lower. Nevertheless these tablets were available especially in the larger packages at a variety of prices most of which were substantially lower than in later 1959. One brand name supplier, Will, had a price for 100's as low as one generic name supplier (Bell-Craig) and lower than another (Gilbert).

For vials of 1, 000, 000 I.U. list prices bore a strong resemblance to those of December 31, 1959 in their division into two groups, 65 cents and 88 cents, with two exceptions, Gilbert's list price of 72 cents and Glaxo-Allenbury's list price of 55 cents, the latter a reduction from 65 cents. Gilbert's list price was higher than that of several brand name suppliers, but, as noted earlier, such prices were subject to larger discounts on sales to retailers.

In June, 1961 list prices for vials of 3, 000, 000 I.U. were identical for four brand name suppliers. List prices for this vial are not given in the Green Book. Gilbert's list price appears to be higher than that of the brand name suppliers but his net price would presumably be lower.

As noted earlier, the Commission only has information for list prices in 1962 from secondary sources. This incomplete information indicates that two generic name suppliers had made further reductions in the prices on the tablet of 500, 000 I. U. by 1962.

5. Newer Penicillins

Patent rights are held on processes for manufacturing the newer penicillins although Frosst informed the Director that it manufactured benzathine penicillin G by a non-infringing process. Potassium penicillin V is sold in Canada by a number of firms which secure supplies from Denmark or Italy, apparently without licences from the Canadian patent holder. It will be recalled that patents on drugs are not granted in Italy.

The Director had found that while costs of basic drugs and prepared dosage forms of the new penicillins varied widely among different sources of supply, list prices of the larger firms in December, 1959 were substantially identical. By June, 1961 some changes in this situation were apparent from the price information obtained by the Commission. Reductions in prices had been made by Abbott, Eli Lilly and Wyeth (the latter did not reduce prices of Bicillin) among the brand name manufacturers and by Gilbert among the generic name manufacturers. The price reductions were of a substantial nature; for example, Eli Lilly's V. Cillin K 200, 000 I.U. formerly listed at \$17.00 for 50 tablets was reduced to \$12.75. Wyeth's Pen Vee Oral formerly listed at \$4.50 for 12 tablets and \$33.75 for 100 was reduced to \$2.70 and \$20.25 respectively. Similar reductions were made by Wyeth in tablets of 400, 000 I.U. and 500, 000 I.U. On the other hand, Ayerst, Beecham and Bristol had not made price changes in their products of this type by June, 1961. Gilbert's list prices which had been \$25.00 for 100 tablets of phenoxymethyl penicillin potassium 200, 000 I.U. and \$40.00 for 500, 000 I.U. in 1959, had been reduced to \$15.00 and \$30.00 respectively for Pen-V-Potassium by June, 1961.

By early 1962, penicillin V potassium was being offered by two more generic name suppliers, Empire and Bell-Craig, at prices lower, and in some instances substantially lower, than the list prices of Gilbert in June 1961. As examples, Empire had a list price of \$9.50 for 100 penicillin V potassium tablets 200, 000 I. U. while that of Bell-Craig was \$8.50.

6. Streptomycin and Dihydrostreptomycin

The Green Book states that the price history of these drugs, which were the next antibiotics to be discovered after penicillin, parallels that of the latter. From an extremely high initial price there were successive declines until by 1954 the drugs became what the Director describes as low-cost. Streptomycin and dihydrostreptomycin are not subject to patent control and are available from a number of suppliers at varying prices. The more recent price information obtained by the Commission does not indicate any significant change from the situation described in the Green Book.

7. Broad Spectrum Antibiotics

Information on five broad spectrum antibiotic drugs is given in the Green Book. These are chloramphenicol, oxytetracycline, tetracycline, chlortetracycline and demethylchlortetracycline. The

patent situation existing at the time of the Director's inquiries is described in the Green Book. The latter two drugs listed above were developed by the American Cyanamid Company, which distributes them under the brand names Aureomycin and Declomycin. Patents on chloramphenicol are held by Parke-Davis but the product is also manufactured in Canada by Fine Chemicals under a compulsory licence. Patents on oxytetracycline are held by Chas. Pfizer & Co. Inc., from which the Pfizer Corp. of Canada imports the drug. Tetracycline is sold by a number of firms although the basic patents are held by Pfizer.

According to the submission made to the Commission by Cyanamid of Canada, American Cyanamid developed the first of the broad spectrum antibiotics, chlortetracycline under the company's brand name, Aureomycin, which was introduced in Canada in 1949 at an initial list price of \$21.40 for 16 capsules. The submission then states:

" . . . The initial price was well below that indicated by the usual considerations , such as estimates of initial production and marketing costs, which promised to be extremely high.

Aureomycin rapidly attained wide usage among doctors over North America. Early in 1949, Parke-Davis introduced another broad spectrum antibiotic, Chloromycetin, and early in 1950 Chas. Pfizer & Co. brought out another, Terramycin. Thus , within about a year and a half, instead of being the only producer of broad spectrum antibiotics, Cyanamid became one of three competing producers.

American Cyanamid Company had gambled that through improvements in processing, production costs could be substantially reduced, and through eventual increased volume of sales, prices could be lowered. It turned out that this gamble was justified, so that by 1953, in the face of intensive price competition from the other producers, the suggested list price in Canada had dropped to \$9.35 for a bottle of 16 capsules - 65% off the initial price. Furthermore, as an element in price reduction, the average prescribed dose was changed in 1952 from 2 grams per day to 1 gram per day."

(Cyanamid brief, p.35; Hearing, pp.1511-12)

Commenting on Cyanamid's policy in pricing new drugs, Mr. R.B. Thompson, Manager, Medical Products Department, said:

"Yes, again it is a very difficult decision for a manufacturer to make in launching a preparation such as Aureomycin as to what price should be set. That is normally done at a time at which scale production -- there is no appreciable scale of production and it is exceedingly difficult to project what the trend of cost will be as the volume rises. It is also virtually impossible to predict the useful market-life of the product and to predict over what period the capital cost of developing the product should be recovered. You may well find a competitor with a different view on the subject."

(Hearing, pp. 1704-05)

In 1954, Cyanamid of Canada introduced another broad spectrum antibiotic, Achromycin (tetracycline), which is claimed to be more stable and less toxic than Aureomycin. Although Achromycin is produced by chemical alteration of Aureomycin and is thus more costly to produce than the latter, it was put on the market at the same price (Hearing, pp. 1513-15). Other companies had been engaged in the development of tetracycline and within less than a year Cyanamid became one of five companies marketing forms of this drug (Hearing, p. 1518).

Subsequently, American Cyanamid developed a new antibiotic, demethylchlortetracycline which was introduced in Canada under the brand name Declomycin in October 1959. While, according to the submission of Cyanamid of Canada, the new drug costs considerably more to make than Aureomycin or Achromycin it was put on the market at the same price (Hearing, p. 1520).

Mr. Thompson of Cyanamid of Canada was asked about the price which the Canadian company pays to the parent company in the United States for the crude drug from which the refined tetracyclines are made which appeared to be higher than the cost reported for one company in the United States for the finished product. Mr. Thompson gave the following evidence:

"MR. THOMPSON: Well, Mr. MacLeod, the price that we pay to our parent company, have been paying, is more than just a basic cost for the bulk crude material.

MR. MacLEOD: Yes.

MR. THOMPSON: It includes -- it is one of the ways in which we contribute to the research programme in our parent company. The methods by which this kind of relationship takes form are changing in the industry and we are perhaps a good

example of that because we will cease - we have already discontinued the importation of materials which you have described and we will now produce it in Canada. We also are now in the process and in fact have been negotiating an agreement on research and development, an agreement between Cyanamid of Canada and our parent organization, so that there will be a separate fee charged for research and development which in the past has been transmitted to the parent company through the medium of raw material purchased, not just tetracyclines, but of other things."

(Hearing, pp.1708-09)

During his appearance, Mr. R. B. Thompson of Cyanamid of Canada was asked to comment on the static price situation with respect to tetracyclines which prevailed from 1954 to 1960. He said that in this period two forces were at work. On the one hand, there was inflation which put an upward pressure on all costs and, on the other, there was active competition among suppliers and a general expansion of the market with the advantage of larger volume (Hearing, pp.1703-04). The inference in Mr. Thompson's evidence appears to be that the two opposing forces offset each other.

Reductions in the prices of tetracyclines were made in Canada in October and November, 1960 after reductions in the prices of similar products in the United States. Pfizer is reported as having made the first move in the United States while Cyanamid of Canada made the first announcement in Canada. Shortly thereafter reductions in prices were made by major competitors and Cyanamid of Canada made a further reduction in its prices to hospitals to the new competitive level (Hearing, pp.1521-22; 1696-97).

The Director had found that despite wide differences in the costs of dosage forms of the broad spectrum antibiotics among different manufacturers, the list prices of the large firms were substantially uniform in 1959. Following the price reductions referred to above significant variations appeared between the list prices of some large suppliers although there was a degree of uniformity in the list prices of some suppliers for some dosage forms but the number of closely related prices was smaller. This was due to the fact that all firms did not reduce their prices by the same percentage. The material in the Green Book (p. 173) for 250 mg. tablets or capsules of broad spectrum antibiotics covering a number of branded products of Bristol, Cyanamid Parke-Davis, Pfizer and Upjohn gives prices from \$9.43 to \$9.45 for 1 tablets and \$56.60 to \$56.70 for 100 tablets. Price lists for the same companies received by the Commission show prices in June 1961 for the

same branded drugs ranging from \$6.60 to \$7.98 in packages of 16 and from \$39.40 to \$56.61 in packages of 100.

By June 1961, Horner was selling chloramphenicol and tetracycline under its own brand names with a list price for the latter below the list prices of tetracyclines distributed by the other large firms. The distribution of tetracycline under its own brand name had also been undertaken by Laboratoire Nadeau Limitee of Montreal by June 1961 at a still lower price.

Gilbert was listed as the only supplier of tetracycline under generic name in the Green Book, but the price lists received by the Commission show that Empire was listing the same drug in 1961. In the case of chloramphenicol Gilbert and Empire continued to list this drug and H. Powell Chemical Co. Limited of Bowmanville, Ontario had this drug in its price lists in June, 1961. The prices listed for tetracycline and chloramphenicol by the generic name suppliers were substantially below the list prices of the larger firms. According to reports appearing in the Canadian Pharmaceutical Journal, (March and April, 1962) Bell-Craig had also become a supplier of chloramphenicol and its prices and those of Empire for the same product and also for tetracycline were lower than those of generic name suppliers in June 1961.

The following excerpt from Business Week, July 7, 1962, indicates that further cuts in the prices of the tetracycline group occurred in the United States in the summer of 1962:

"A second wave of drastic price cuts swept the drug industry this week when Chas. Pfizer & Co., Bristol-Myers Co., and American Home Products' Wyeth Laboratories slashed synthetic oral penicillins by 15%-24%.

The cutting started June 15, when American Cyanamid's Lederle Laboratories startled the industry by a 15% price cut on its broad-spectrum tetracycline antibiotics. Pfizer, Eli Lilly, and Olin Mathieson's Squibb division promptly tagged along, and there are indications that Upjohn Co. will do the same."

A report that Cyanamid of Canada Limited had reduced the prices of some of its antibiotics was contained in the August 1962 issue of Drug Merchandising:

"LEDERLE LOWERS ANTIBIOTICS PRICES

Montreal -- Cyanamid of Canada Ltd. announces that prices of a number of Lederle broad spectrum antibiotics have been reduced. Products affected include: Achrocidin syrup and tablets; Achromycin capsules and oral suspension; Achromycin V capsules, syrup and pediatric drops; and Achrostatin V capsules.

The company reports that the most significant factor underlying these price changes is the completion of its new Canadian facilities for the fermentation of crude materials used in the production of broad spectrum antibiotics. Located at the Welland, Ont., plant, these facilities make possible for the first time the fully integrated production of tetracycline [tetracycline] in Canada."

Pfizer Canada's Pharmaceutical Price List, effective November, 1962, announced reductions in its list prices for Terramycin and Tetracyn capsules, syrup, and pediatric drops from the levels previously in effect. For Terramycin capsules, 250 mg., the reductions were 12.9 and 11.9 per cent according to quantity; for Terramycin syrup, 22.3 and 23.9 per cent; and for Terramycin pediatric drops, 12.1 per cent. For Tetracyn capsules, 250 mg., the reductions were 24.2 and 23.4 per cent; for Tetracyn syrup, 26.1 and 28.1 per cent; and for Tetracyn pediatric drops, 19.4 per cent.

8. Other Antibiotics

The Green Book contains information about a number of other antibiotics but it is not considered necessary to include in this report details of the price changes which are contained in the price lists received by the Commission. List prices of some of the drugs in this group were reduced substantially between December 1959 and June 1961 while for others there were no changes in prices. In the case of bacitracin ointment, and neomycin sulphate ointment, several generic name distributors listed these products in June, 1961 at prices usually lower than those of larger firms.

9. Tranquillizers

Information about a considerable number of ataraxic or tranquillizer drugs is contained in the Green Book. The subsequent price history of each of these will not be described here but reference will be made only to those in connection with which developments of some significance are shown in the later information received by the Commission.

(a) Chlorpromazine

Dosage forms of this drug are sold in Canada by Poulenc under the brand name, Largactil. It is pointed out in the Green Book that Poulenc's selling prices are progressively lower as larger quantities are purchased and that the Company follows a policy of selling at a special low price to government departments and psychiatric hospitals regardless of the quantity purchased. At the time of the Director's inquiries Gilbert and Empire were offering chlorpromazine at list prices substantially lower than those of Poulenc. By 1962, Bell-Craig was offering chlorpromazine at list prices lower than those of Gilbert and Empire in June 1961. Another supplier, Paul Maney, was offering the drug under the brand name, Chlor-Promanyl, at higher list prices than those of Bell-Craig in 1962 and of Empire and Gilbert in 1961.

(b) Meproamate

As mentioned in the Green Book this drug is distributed by a number of firms under brand names and by its generic name. Some of the brand names are Miltown (Ayerst), Trelmar (Elliott-Marion), Equanil (Wyeth) and Neo-Tran (Neo Drug). At the time the Director made his inquiries there was a wide difference between the list prices of brand-named dosage forms of meproamate and generic-named forms. For example, as shown on page 193 of the Green Book, the list price of Dymond for 100 tablets of 400 mg. was \$4.00, whereas the list prices of 50 tablet packages under brand names ranged from \$5.00 to \$6.00. Between December 1959 and June 1961 reductions had been made in the prices of almost all brands of meproamate and prices of dosage forms under the generic name had also been reduced. In the case of the 400 mg. dosage form, list prices for brand name forms ranged from \$4.40 to \$5.00 for 50 tablets while prices of the drug per 100 tablets under generic name were \$1.80 (Empire), \$2.70 (Gilbert), \$3.80 (Powell) and \$8.00 (Mowatt & Moore). Partial price information for 1962 indicates that early in that year Bell-Craig had a list price of \$1.60 per 100 tablets for the same dosage form.

(c) Promazine

This drug is also sold by a number of firms under brand names and by other firms under its generic name. In addition to the suppliers listed on pages 197 and 198 of the Green Book ⁽¹⁾,

(1)

The Green Book, p.198, incorrectly states the list price of Will's Promwill, 50 mg., to be \$56.00 per 1,000 in December 1959. Will's catalogue shows the price as \$52.00.

Table 20

LIST PRICES OF CORTICOSTEROID TABLETS
DECEMBER 31, 1959 AND JUNE, 1961

(List prices in dollars, 100 tablets)

	<u>Brand name</u>	<u>Dec. 31, 1959</u>	<u>June, 1961</u>
<u>Cortisone (25 mg.)</u>			
Bell-Craig	*	-	16.50
Empire	*	-	16.00
Gilbert	*	23.00	15.00
Merck	Cortone	23.00	23.00
Schering	Cortogen	23.25	23.25
Upjohn	*	23.00	23.00
<u>Dexamethasone (0.5 mg.)</u>			
Anglo-French	Dexacortisyl	19.90	19.90
Merck	Decadron	19.90	19.90
<u>Dexamethasone (0.75 mg.)</u>			
Merck	Decadron	29.80	29.80
Schering	Deronil	29.80	29.80
<u>Hydrocortisone (20 mg.)</u>			
Bell-Craig	*	-	17.00
Empire	*	-	16.50
Gilbert	*	24.00	15.00
Merck	Hydrocortone	29.80	29.80
Pfizer	Cortril	29.77	29.77
Upjohn	Cortef	29.77	29.77
<u>Methylprednisolone (4 mg.)</u>			
Upjohn	Medrol	38.35	38.35
<u>Prednisolone (5 mg.)</u>			
Anglo-French	Precortancyl	33.12	22.70
Bell-Craig	*	-	8.00
Empire	*	-	8.00
Gilbert	*	18.00	10.00
Parke-Davis	Paracortal	32.80	13.75
Powell	*	-	12.00
Pfizer	Delta-cortril	33.10	22.70
Schering	Meticortelone	33.13	22.70
Upjohn	Delta-Cortef	33.10	22.70

Table 20 (cont'd)

LIST PRICES OF CORTICOSTEROID TABLETS
DECEMBER 31, 1959 AND JUNE, 1961

(List prices in dollars, 100 tablets)

<u>prednisone</u> (5 mg.)	<u>Brand name</u>	<u>Dec. 31, 1959</u>	<u>June, 1961</u>
Anglo-French	Decortancyl	33.12	22.70
Bell-Craig	*	-	7.50
British Drug Houses	*	-	8.00
Can. Pharmacal	Precort	-	**
Elliott-Marion	*	22.80	13.50
Empire	*	-	7.20
Frosst	Colisone	22.80	22.80
Gilbert	*	17.00	10.00
Intra	*	13.75	8.00
Jamieson	*	-	5.55
Maney	*	-	11.00
Merck	Deltra	33.12	22.70
Parke-Davis	Paracort	32.80	13.75
Schering	Meticorten	33.13	22.70
<u>triamcinolone</u> (4 mg.)			
Cyanamid	Aristocort	38.39	38.39
Squibb	Kenacort	38.40	38.40

* Marketed under the generic name.

** Canada Pharmacal did not list prices for 100's but only for 25's, 250's and 500's.

Source: The information condensed in this table has been taken from the price lists of the manufacturers concerned.

Paul Maney and Moore-Thompson-Clinger were distributing promazine under brand names and Gilbert under the generic name.

Differences in prices between the drug sold under brand names and under generic name of somewhat the same order as those mentioned above in the case of meprobamate are shown in the information contained in the Green Book. The same situation is revealed by the price lists received by the Commission for June 1961. The only substantial price reductions had been made in the interval by one brand name and one generic name supplier. Moreover Empire was listing promazine in its price lists by June 1961 at prices lower than those of any other supplier.

10. Corticosteroids

The Green Book at pages 50 and 51 provides some information about corticosteroids but the only details given about costs and prices relate to Schering's prednisolone sold under the name Meticortel. As corticosteroids were among those drugs referred to at hearings held by the Commission some information on their list prices is presented in Table 20. In order to simplify the presentation only prices for packages of 100 tablets are shown.

In 1959, cortisone was being offered by Merck and Schering under brand names and by Upjohn and Gilbert under its generic name. While the list prices of all four suppliers were virtually the same for a package of 100 tablets the net price of Gilbert was probably lower, as this firm granted larger discounts than the usual 40 per cent. By June 1961, Merck and Upjohn had not changed their list prices, but Gilbert's price had been reduced by about one-third and two other suppliers, Bell-Craig and Empire, had entered the market at prices somewhat above Gilbert's but substantially lower than those of Merck, Schering and Upjohn. Information available for 1962 indicates that Bell-Craig had made a reduction in its prices.

Dexamethasone is distributed only under brand names by three suppliers only one of which, Merck, supplies the drug in both dosage forms listed. Prices per 100 tablets were uniform for each dosage form.

In 1959, hydrocortisone was supplied by three firms under brand names and by Gilbert under its generic name. Pfizer and Upjohn had identical prices for packages of 100 tablets while Merck's price was 3 cents higher. The list price of Gilbert was 19 per cent lower. By June 1961 the prices of the brand name products had not been changed but two new suppliers, selling under generic name, had entered the market at prices lower than Gilbert's 1959 prices and the latter had made a substantial reduction in its list price. One of the new entrants, Bell-Craig, had made a reduction in its prices by the early part of 1962.

Prednisolone was supplied by five firms under brand names in 1959, and by Gilbert under its generic name. The list prices of brand name suppliers were the same or very similar, ranging from \$32.80 to \$33.13 while that of Gilbert was about 45 per cent lower. By June 1961, four of the brand name suppliers had identical prices about one-third lower than in 1959, while the fifth, Parke-Davis, had reduced its price by more than one-half. Three suppliers, Bell-Craig, Empire and Powell had entered the market and the first two had prices lower than the new list price of Gilbert. By early 1962 Bell-Craig had made a reduction in its list price of prednisolone.

In 1959, prednisone was being supplied by five firms under brand names and by three firms under its generic name. Four of the five brand name firms had the same or closely similar prices ranging from \$32.80 to \$33.13, while the fifth, Frosst's Colisone, had a list price of \$22.80, the same as that of Elliott-Marion's prednisone. By June 1961, five additional firms were supplying the drug under its generic name and one additional firm was supplying under a brand name. Frosst had made no change in its price of Colisone, but three of the other brands were priced at slightly below the same level, while Parke-Davis had reduced its price of Paracort to the lowest level at which the drug had previously been offered under its generic name. However, by June 1961 the list prices of the generic name suppliers were substantially lower as shown above. Information available to the Commission for 1962 indicates further substantial reductions in prices by Bell-Craig and Empire.

CHAPTER XVIII

FACTORS HAVING AN INFLUENCE ON PRICES

1. The Effect of Patents on Prices

In the Director's view, the existence of patent rights has an influence on the prices of certain drugs. His conclusions were stated as follows:

"467. The information obtained in this inquiry appears to indicate that, at the manufacturers' level, prices of certain drugs are affected by the control over the manufacture, distribution and sale of such drugs exercised through patents. The provisions of the Patent Act relating to compulsory licences appear to have proved ineffectual to combat this situation and the clear intent of the Act has been frustrated. This conclusion is not intended to imply any opinion about patents as such, it is intended simply to indicate that, in relation to the sale of drugs in Canada, patents have been and are being used to create monopolistic situations which the Canadian law appears to have been designed to prevent. The control exercised over the manufacture, distribution and sale of certain drugs through patents has virtually eliminated price competition in respect of such drugs and has encouraged other forms of competition which, while possibly bringing other benefits to the public, have resulted in prices being increased rather than decreased. Practices which are quite legal and unobjectionable in themselves (promotion, use of trade names, and the like) appear to have been carried to extremes because of the insulation of certain sectors of the industry from price competition by reason of the control exercised through patents."

(Green Book, pp.257-58)

Several witnesses at the Commission hearings made reference to this question. Mr. J. W. T. Michel, Commissioner of Patents, Department of the Secretary of State, reading from a prepared statement, said:

" . . .

I should only add, however, that in my opinion the patent system, if it is a factor in the high price of drugs, it certainly is not the main factor I am wondering if too drastic a treatment of the patent system would not harm the modest, but bona fide, efforts of those doing research in Canada more than the quota [portion] of the high price of drugs which might be attributed to the patent system."

(Hearing, pp.307-08)

The brief of the Canadian Pharmaceutical Manufacturers Association denied the correctness of the Director's conclusions concerning the influence of patents on prices, as appears from the following excerpt:

"We suggest that the conclusions concerning patents are based on opinion and not fact. Furthermore, it is significant that of all the representations concerning patents made to-date before this Commission, only one person, the Commissioner of Patents, was qualified to speak on the subject. The remainder largely used the wording of the green book as their sources of information.

Firstly, in respect to prices, the Commissioner of Patents apparently does not agree that patents have a major bearing on prices. In his testimony, Mr. J. W. T. Michel stated that the patent system, if it is a factor in the price of drugs, 'it certainly is not the main factor'.

It is an economic fact that any company introducing a drug to the market must base its price on those of other products already on the market which compete with it in the therapeutic class concerned. There is virtually no specialty drug on the market today whose therapeutic effect cannot be approximated by some other drug. Regardless of how strong the patent on a new drug, it does not by any stretch of the imagination give that company a free hand to inflate price beyond reason. If that were done, there is no doubt that detail men representing competitors' products would bring this point to the attention of the medical profession.

If the process involved in making the product is too costly in relation to that of its competitors, then the company must find a more economical means to bring down

costs so that the end price will not be too far out of line. This factor can mean the difference between a large-volume or low-volume product, regardless of the patent."

(Association brief, pp.72-73; Hearing, pp.1973-74)

Mr. Hazen Hansard, Q.C., counsel for several drug companies, said:

"I don't like to intervene with somebody else's witness, but I have had a certain amount of experience, not recently, with patents, and of course the thing that overhangs the whole situation is the compulsory licence. The minute somebody comes out with something and tries to charge more . . . than should be charged for it, that attracts somebody else, and a compulsory licence comes into it, and that provision for compulsory licence is there. One of the reasons that there have been relatively few compulsory licences - but there have been a good many - one of the reasons why that is so is because responsible people who have been bringing out these things have not taken advantage of the situation and they have been supplying the market at prices which people in the industry know what it costs to make these things, prices which are related to these costs. Therefore if someone is making more money than he should, he will have compulsory applications, compulsory licences on his tail right away, and the fact that that has not happened is an indication it has not been done."

(Hearing, pp.1976-77)

Mr. Hume, counsel for C.Ph.M.A., argued as follows in answer to a question asked by Mr. Whiteley:

"MR. WHITELEY: What do you consider in a situation where a new product is in effect a radically new approach to the condition that is going to be treated?

. . .

MR. HUME: I think the simple answer, Mr. Chairman, to Mr. Whiteley's inquiry is [that, with respect to] a brand new product, a monopoly does give an advantage, and that is what the Patent Act intends. That is what patents do. . . . "

(Hearing, pp.1974-77)

Jules R. Gilbert, President of Gilbert & Company, was questioned at some length concerning the effect of patents upon his company's business. His evidence may be summarized as follows:

His company manufactures on its own premises about 70 per cent of the finished drug products sold by it. It does not make any basic drugs, importing at least 95 per cent of its requirements from outside Canada. He stated that, in respect of drugs for which patents are held, his company had difficulty in buying them in Canada. He cited the drug chloramphenicol, stating that the price charged by a Canadian company producing under a patent licence was \$208.00 a kilogram, that this company would not sell to him, but that he could buy the drug in Italy for about \$34.00 a kilogram. Another instance was meprobamate, whose price by the same Canadian company was, he said, about five times what he regarded as normal. Nor would this Canadian company sell meprobamate to him.

His company had no difficulty in purchasing drugs that were not subject to patents and for such drugs the prices charged by the same Canadian company were very close to the duty paid world price. Where patents existed, however, there was a tremendous spread between the prices charged by Canadian companies and those available abroad, particularly in Italy, but also in Denmark, Switzerland, and for chloramphenicol, Hungary. (Hearing, pp.2828,2835-42).

Mr. Thompson of Cyanamid gave two reasons for the reductions, in total a very large percentage, which had occurred over the years in respect of the price of penicillin. One was a much improved method of production and the other was the development of large over-capacity which in time led to many producers being forced out of business. He did not agree with the suggestion of the Director's representative that the reason there had been no reduction in the prices of broad spectrum antibiotics in the United States or Canada up to 1960 in contrast to the price record of penicillin, was that the broad spectrums were tightly controlled by patents, which was not the case with penicillin (Hearing, pp. 1522-23; 1700-04).

When a drug manufacturer engages in expensive research for the development of new drugs he does so in the hope that his research efforts will be profitable. Sometimes a specific research project ends in failure and is abandoned. The profits on the successful ventures must be at least more than sufficient to cover the losses on those that are unsuccessful, if the overall result is to be profitable. The profits on a successful drug depend, of course, on the volume of sales and the price at which it is sold relative to the total costs of production and sale.

A manufacturer must consider a number of factors when setting the price of a newly developed drug for which he has obtained

a process patent. Among these are the costs of research, of raw materials, of manufacture, of promotion and of advertising. He must also consider the likely volume of sales, and for this purpose account must be taken of competing or substitutable products and the degree to which they really are competitive or substitutable. On this question will depend the degree of benefit conferred upon him by the monopoly given by his patent. If the drug has unique properties and appears likely to have widespread use he can set a monopoly price, much higher than if closely competing products are on the market. Even where he has a monopoly position, however, he must bear in mind that a too high price may invite applications for compulsory licences. He must also estimate for how long a period his product is likely to be alone in the field.

The foregoing analysis indicates that the manufacturer of a new drug protected by process patent is seldom completely free to set a price which has regard only for the maximum return any price might earn. Nevertheless it is the Commission's opinion that patents do give the holders the power to charge substantially higher prices, varying according to circumstances, than would otherwise be the case. It may be said with some justification that this situation is the normal result of the grant of any patent. In Canada, however, the special situation created by the statutory provision for compulsory licences must be considered. This provision is clearly designed to keep prices of patented drugs as low as possible while still giving the inventor due reward for his research.

2. The Relationship of Prices to Costs

The evidence available to the Commission in the inquiry generally supports the view that the manufacturers' costs, particularly for products distributed through drug stores, are likely to have little relation to the prices of prescription drugs.

Dr. Brian Dixon, Assistant Professor of Economics at Queen's University, and a consulting economist, prepared a study in 1960, entitled "An Economic Analysis of the Pharmaceutical Manufacturing Industry in Canada", from which the following excerpt is taken:

"It will be observed that particularly in the early stages there is little if any relation between costs and the price set. This is reasonable under any marketing circumstances in that the price should be demand-oriented rather than cost-oriented, but particularly in the case of the pharmaceutical industry in common with some others, the presence of a preponderance of joint costs which are inseparable as far as individual products are concerned makes

any attempt at individual product cost pricing pointless and purely arbitrary."

(Appendix C to the C. Ph.M.A. brief, p.30)

Mr. J. R. Gilbert, President of Gilbert & Company, stated his view:

"MR. MACLEOD: Do you feel that promotional costs are a large factor in the present prices charged for brand name drugs?

MR. GILBERT: I don't think there is any relationship to it. I think prices are set on the basis of what the market and the conditions will bear and what they can get from the public. . . . "

(Hearing, p.2881)

A very different attitude on the part of pharmaceutical manufacturers, with respect to some types of products, was described in some detail in the brief of the C. Ph. M. A. :

"Allied to this product diversification, is the fact that many pharmaceutical manufacturers carry 'public service' products on which they actually lose money or break even on cost. Some of these drugs are actually given away free. These are largely products discovered in pharmaceutical laboratories which have a limited use in that they are often for rare diseases or ailments.

In many cases these 'public service' products are the result of extensive research, but for a variety of reasons have a small demand. Aldosterone is an excellent example. Used to combat diminished or absent adrenal functions, this mineralocorticoid was isolated and synthesized by Ciba. While of major physiological importance, it has as yet a limited therapeutic use.

Few Canadians have cause to fear venomous snakes in this country. Yet the occasional near fatality does occur, and it is for this reason that Wyeth maintains a stock of Antivenin, the anti-snake bite serum. Roche, on the other hand, produces a chemotherapeutic agent called 5 FU. Administered in the treatment of certain cancers, it is given free to qualified clinicians.

Warner-Chicott did considerable research on Releason, only to find that it is extremely difficult and costly to manufacture. Initially used in threatened abortion, it has now been found helpful in alleviating scleroderma, a rare disease causing hardening of the skin and for which there is no known cure. The company loses money every time it makes a sale of this product.

Mead Johnson's Lofenalac is truly a life-saving boon to sufferers of phenylketonuria. This is a rare disease of children which, if untreated, will eventually cause permanent and fatal damage to the brain. Fortunately, this disease can be easily detected and, if determined in the early stage, Lofenalac will actually prevent the brain damage, permitting the child and later the adult to live a normal life. This is the only product of its kind available in Canada. Yet Mead Johnson makes it available at cost, taking no profit whatever on the product.

While products such as these are not commercially profitable, companies keep them in stock for humanitarian reasons. In most cases, the use is so limited that the so-called prestige value bears no relationship to the cost involved.

A recent survey of 39 companies indicated that 22 of these firms carry products of this type. During 1960, these 22 manufacturers supplied a total of 112 public service products at a total volume of about \$400, 000 for an average of some \$3, 571 per product for the year. One company with 10 such products reported that its individual product sales ranged from 19 to 7, 540 packages during the 12 month period. "

(Association brief, pp.12-13)

The Commission agrees with Professor Dixon's view that, particularly in the early stages of a new drug's appearance on the market there is little, if any, relation between costs and the price set. It is true, of course, that the prices realized by a manufacturer for his whole range of products must be sufficient to cover all his costs. Otherwise the manufacturer would be losing money, and if this situation continued he would eventually become bankrupt. The manufacturer, in setting his price, must consider many questions, some of which have very uncertain answers. It is reasonable to believe that a manufacturer exercising his judgment on these questions will normally set the price to maximize profits. In other words the decision rests essentially, not on the manufacturer's costs, but on what the market acceptance is expected to be. (As the drug industry and market are constituted there is seldom sufficient competitive pressure from similar or substitutable products

to force a manufacturer of a new drug, for which substantial sales are in prospect, to fix a price that will merely cover his costs, though frequently the existence of similar or substitutable products may lead to a lower price being set than would otherwise be the case.)

The brief of Cyanamid of Canada, in discussing prices set by Cyanamid for Achromycin and Declomycin supports the Commission's conclusion that costs do not determine the price of a new drug. The brief states that by the time Achromycin (tetracycline) was about to be placed on the market the price of the company's earlier product Aureomycin (chlortetracycline) had reached an established level of \$9.35 for 16 capsules. Achromycin was considerably more expensive to make than Aureomycin and required very heavy promotional expenditures to introduce it to the medical profession. It was also more stable and less toxic than Aureomycin. Nevertheless it was introduced in Canada in February 1954, at exactly the same suggested list price as Aureomycin, viz., \$9.35. Similarly, when Declomycin (demethylchlortetracycline) was introduced in Canada in October 1959, though it was a superior antibiotic and cost considerably more to make than Aureomycin or even Achromycin, the price set for it was exactly the same as for the two earlier drugs (see Cyanamid's brief, pp.36-38).

3. The Influence of Competitive Products on Prices

Professor Brian Dixon's study contains the following analysis of the influence of competing products on price behaviour in the drug industry:

" . . . The main pressure for price reductions comes from competitive development of similar products or from improved production techniques which enable the competitors to reduce the price in an attempt to take over more of the market from the introducer of a particular product. These circumstances tend to create a pricing pattern which is somewhat dissimilar to other industries, at least superficially. The initial stages are the same. A given price to start, set as far as can be ascertained on the basis of an estimate by the introducing firm of the substitutes and their prices and the demand pressures which exist. After a period of initial pricing, the introduction or improvement of competing products reduces the price to a second level, where it quite often stays, rather than continuing to reduce, unless the item becomes a staple drug. The more typical pattern seems to be that the drug is displaced by a product which is significantly better in performance. At this point the conventional techniques in other industries of sharp price reductions have no particular effect. The consumer is not interested in the

inferior product at any price, except in fringes of the market. Thus there is no point or purpose in the manufacturer reducing price at this stage, no increase in sales can be expected as a result. Thus price rigidity sets in at this point, which is not however the result of monopolistic or collusive activity to 'hold up' the consumer, rather it is because of consumer indifference to the product at all because of superior substitutes. The manufacturer can hold his price here as long as he wants, but as long as his competitors continue to produce innovations, he will sell very little of his product. His only competitive solution is to develop and introduce innovations himself. "

(Appendix C to the C.Ph.M.A. brief, pp.29-30)

Professor Dixon's opinion, as given in the foregoing excerpt, must be considered together with the evidence presented in the Green Book on the price histories of several antibiotics including broad spectrum antibiotics. The histories of the prices of the older penicillins (Green Book, pp.158 and 162), of streptomycin and dihydrostreptomycin (Green Book, p.168), of Chloromycetin and Aureomycin (Green Book, p.175) indicate that prices frequently have moved in a downward direction over a longer period than Professor Dixon's analysis might suggest. This conclusion is further supported by the evidence of more recent list prices obtained by the Commission, which is set out in Chapter XVII of this report and which indicates later price reductions than those noted in the Green Book.

On the other hand a reduction in the price of a drug may not affect sales in a significant way. Mr. R. B. Thompson of Cyanamid, gave evidence concerning reductions in the prices of broad spectrum antibiotics in 1960 and 1961, when a price cut by his company was followed by price cuts by other manufacturers. Despite the reduction in price, Mr. Thompson testified that his own company's total number of antibiotic doses had remained approximately constant. If other companies had not followed his reduction so quickly his sales might have increased (Hear pp.1587-90).

Mr. Thompson discussed at some length the question of competitive products. The following excerpts from his testimony illustrate his views:

"... I said that I have the choice of attempting to sell my antibiotics at a higher price than my competitor. I have the freedom to make this decision. His product is, let us say, ten per cent lower than mine. I can say to myself that I think I can still sell my product ten per cent higher and the extra income will be used to launch a tranquilizer but I find from the effect of competition that I cannot do that. I could not maintain my sales against ten per cent differential

even if I spent the entire ten per cent on promotion so I have no choice. I have to reduce my price to meet the competitive level and still find some other way to market my tranquilizer. Usually this means a capital investment, . . . "

(Hearing, p.1592)

"... broad spectrum antibiotics include not just the tetracycline[s] but chloramphenicol and this range must compete with the other antibiotics which overlap into the range of treatment with the tetracycline antibiotics. If you look at the width of the spectrum for penicillins and then superimpose on that the width of spectrum for tetracyclines you will find a substantial area of overlap. I think it is a very difficult decision for a practising physician to make, whether to prescribe penicillin for an ill patient in the belief that the organism probably falls within the penicillin spectrum or whether to purchase extra insurance for his patient by covering the broader range by the use of some broad spectrum antibiotic. These two different classes of antibiotics are constantly in competition with one another and the physician's office, I suggest, this is the point where the decision is made on balance, whether to use the tetracycline for treatment or a penicillin. I don't think it is fair to say that the tetracyclines are closely controlled or restricted because the manufacturers engaged in marketing these drugs are not isolated in the antibiotic field. They need to compete with all of the others."

(Hearing, pp.1702-03)

"MR. MACLEOD: . . . You insist that you think that there is price competition in the sale of broad spectrum antibiotics.

MR. THOMPSON: I do believe that, Mr. MacLeod.

. . .

MR. MACLEOD: I think you suggested, too, that even the older penicillin was a competitor of the broad spectrums.

MR. THOMPSON: Yes indeed.

MR. MACLEOD: But its price is far below that of the broad spectrums.

MR. THOMPSON: Yes, and I think it may also be said that in the case of many physicians, the broad spectrum antibiotics that we are talking about are worth the difference.

MR. MACLEOD: But the lower price of the substitute product does not bring down the price of the broad spectrums.

MR. THOMPSON: It has a very definite influence, I think, on the price of the broad spectrums, and I think there is a pattern in their relationship. There are physicians who are using more penicillin and less tetracycline now for this reason, due to the ---

MR. MACLEOD: Because of the price?

MR. THOMPSON: Pardon?

MR. MACLEOD: Because of the difference in price?

MR. THOMPSON: Yes.

THE CHAIRMAN: You mean, Mr. Thompson, that a number of physicians make the choice to use penicillin which in their own opinion may not be as effective [but] because of the difference in price, they would prefer to prescribe it for certain patients.

MR. THOMPSON: Yes to some extent. It is a question of how ill the patient is and what is the extent of the risk. If the patient is not seriously ill, the physician may well start with penicillin knowing there is a greater possibility with penicillin if the patient has an infection, that penicillin would reach, and also knowing that there is a risk of a penicillin reaction in a small percentage of cases, and he may prefer to take those risks knowing that the patient is not seriously ill, but the choice is also there to switch to a more costly and more potent drug at a later date."

(Hearing, pp.1710-11)

Mr. Thompson further testified as to the substitutability

(a) of Aureomycin (chlortetracycline) for Achromycin (tetracycline):

"MR. FRAWLEY: Well, Mr. Thompson, if you let the cost factor get into your pricing to a larger extent, wouldn't the doctor who was anxious, as some of them I am sure are, to put his patient to the least possible drug expense, would he not be able to prescribe Aureomycin rather than Achromycin? He might think in his own mind that the Aureomycin would give his patient the same benefit as the more expensive to make drug.

MR. THOMPSON: If he feels that way, Mr. Frawley, I would like to have an opportunity to talk to him about the differences between Achromycin and Aureomycin which he presumably does not understand.

MR. FRAWLEY: Then my question was a very ill-advised one. There is no such thing as a doctor prescribing Aureomycin for the same condition or approximately the same condition rather than Achromycin?

MR. THOMPSON: In all fairness there is an occasional case where that is true. . . .

In these rare cases Aureomycin might well be the drug of choice, . . . "

(Hearing, pp.1582-83)

(b) of one brand of tetracycline for another, e.g., of Bristol's Polycycline, Pfizer's Tetracycline or Squibb's Steclin to Lederle's (i.e. Cyanamid's) Achromycin:

"MR. FRAWLEY: And they are all Tetracycline U.S.P. They wouldn't be Tetracycline U.S.P. in Canada would they?

MR. THOMPSON: We don't use U.S.P. in Canada. There is only one product that is put up in a soft elastic capsule, and they are not all the same for that reason. There is a difference right there that I think may well be significant. If you suggest that these products are all identical, I find it hard to agree with you.

MR. FRAWLEY: You cannot agree that they are identical?

MR. THOMPSON: No.

MR. FRAWLEY: This man shouldn't be calling them all Tetracycline U.S.P. then?

MR. THOMPSON: They may contain tetracycline but the availability of that drug to the patient is not necessarily described by that.

MR. FRAWLEY: I don't quite know what that means. The 'availability to the patient' is what?

MR. THOMPSON: The physiological, the availability of the drug Mr. Frawley, varies according to the way it is prepared in the dosage form. They may all contain the same dr

(Hearing, pp.1593-94)

(c) of Chloromycetin (chloramphenicol) for Declomycin (demethylchlortetracycline) and Achromycin (tetracycline):

"MR. THOMPSON: Yes, we have repeatedly attracted the attention of physicians to the reduced overall cost of treatment of the patient using Declomycin as compared with another broad spectrum antibiotic with which it is highly competitive, and I refer to chloramphenicol.

This requires an understanding of fact that Declomycin persists longer in the system after dosage stops, and of the fact that a smaller milligram dose of Declomycin is effective, and then having regard for the cost per capsule. These three factors have to be taken together in order to clarify this point, and this we find the physician very much interested in.

I am sorry I do not have an example of this sort of thing with me, but this is a straight calculation in economics and a typical course of treatment and it has regard for the overall cost of the treatment for one drug as compared to the other. Just price competition.

MR. WAHN: Could this be considered direct evidence of price competition in the field of antibiotics?

MR. THOMPSON: Oh I think so. Very much so."

(Hearing, pp.1551-52)

"MR. MACLEOD: Is tetracycline still a large selling drug?

MR. THOMPSON: Yes, it is an important one. Declomycin has been gaining significantly, of course, at the expense of tetracycline and tetracycline is declining.

MR. MACLEOD: Well tetracycline has had a reasonably long life even up to this time.

MR. THOMPSON: Oh yes it has indeed. It is very definitely being challenged. It has been since 1959. We expect that the volume of tetracycline will continue to decline as physicians come to prefer newer antibiotics such as demethylchlortetracycline.

MR. MACLEOD: Chloramphenicol, of course, is an example of a drug having a long useful life.

MR. THOMPSON: I would have to refer you to Parke, Davis who are the people who introduced that. My understanding is, from sources I read, it has fallen somewhat into disfavour due to side effects. I read this recently in a medical journal.

MR. MACLEOD: Do you find chloramphenicol and chloromycetin are much in competition with you?

MR. THOMPSON: Very definitely.

MR. MACLEOD: And have been for a period of something like 12 or 13 years now?

MR. THOMPSON: Yes, it is becoming increasingly so as its position saleswise on the market is becoming established. When new products are introduced, Mr. MacLeod, there is invariably a difference of opinion as to how much should prevail among the companies sponsoring each drug. This is always resolved in the marketplace by the preference of the users. Sometimes it takes several years for this sort of situation to stabilize. "

(Hearing, pp.1705-06)

Mr. J. W. Richardson, Vice-President, The Manitoba Pharmaceutical Association, testified concerning the displacement of Aureomycin (chlortetracycline) and Terramycin (oxytetracycline) by tetracycline:

"MR. MACLEOD: Now, the opinion has been expressed at various times that sometimes when the main drug itself falls into disuse or relative disuse combinations of it will be continued to be used for years. As I understand it, Aureomycin and Terramycin are being displaced to a certain extent by tetracycline, but drops or ointments or lotions and those types will be widely sold. First of all, is my premise in that question correct, that Aureomycin and Terramycin are being displaced by tetracycline?"

MR. RICHARDSON: Yes, that is correct.

MR. MACLEOD: What about the subsidiary products?

MR. RICHARDSON: They also go by the board.

MR. MACLEOD: Do they have a tendency to have a longer life than the main product itself? Say, for example, 250-milligramme capsules as compared to, say, eye-drops?

MR. RICHARDSON: No.

MR. MACLEOD: You would say they would be the same?

MR. RICHARDSON: In some instances shorter.

THE CHAIRMAN: You mean there is no pattern?

MR. RICHARDSON: Not for the one chemical, no."

(Hearing, p.688)

The following excerpt from the evidence of Mr. S. N. Conder, General Manager of the C. Ph. M. A., relates to the question of competitive products:

"MR. WHITELEY: Take the situation where the broad spectrum antibiotic as compared with the narrower line, what relationship would there be there in terms of price?"

MR. CONDER: Relationships there in terms of price might be based on a considerable number of factors. It could be based, for example, on the cost factor, and it might conceivably cost - it must cost more, rather, to manufacture a broad spectrum antibiotic than one of the narrower antibiotics. In dealing with the broad spectrum antibiotic you are introducing something brand new to the market at that time.

MR. WHITELEY: This was the point I originally raised.

MR. CONDER: Whereas the narrower ones will have been on the market for some time and used widely, and of course a price could be much lower.

THE CHAIRMAN: We had one of the best examples I think in [chlor]tetracycline or Aureomycin.

MR. CONDER: Yes, that is correct.

THE CHAIRMAN: Which was in a position of practical monopoly for about a year, and that was a drug which apparently had very wide acceptance, and was considered to be much better than anything else on the market at the time. True, penicillin was there, but Aureomycin or [chlor]tetracycline was considered to be much more effective, and therefore it had practically a monopoly.

I think the sort of question in Mr. Whiteley's mind is where you have that kind of situation is there any compelling price limitation arising from a competitive drug?

MR. CONDER: I think they must always consider a price competition from the other product on the market regardless of how effective this new medication may be, because it does take time for the medical profession to come around to prescribing a new drug and dropping all the old drugs which it has been using for many years. If the company inflates the price too high or it is too far out of reason, it will take that much longer before it can get such a complete acceptance of the new product.

THE CHAIRMAN: On a question of that kind, it seems to me you have something that is completely new, as Mr. Whiteley was suggesting, and there isn't any price competition from other products that you can pin down and say 'Now, if I charge another 50 cents a 100 for these tablets I won't be able to sell because this other drug is in competition'. Competition is not close enough.

MR. CONDER: That is true."

(Hearing, pp.1974-76)

From all the foregoing evidence as well as what is contained in the Green Book, the Commission is of the opinion that the drug manufacturer is seldom completely free to fix his prices without regard to the possibility of losing part of his sales to competitive or substitutable products. However, it seems clear that one drug may differ from another or even all others in its uses and in its effects upon patients. If this is true as between the different brands of the same drug, tetracycline, as was stated in evidence for the manufacturers, it is obvious that the differences between drugs that differ widely in their active ingredient, e.g., penicillin, chlortetracycline, chloramphenicol and demethylchlortetracycline, must be much greater. Thus, while the prices of drugs which are close therapeutic substitutes for a given drug will have a considerable effect upon the price of the latter, so that it is likely that there will not be much, if any, discrepancy between the prices of products in the group, frequently this condition of close therapeutic substitutability does not exist. This is particularly true when a completely new drug appears on the market, one with greater potency, usefulness, or freedom from side effects than any of its possible substitutes. In all such cases, their prices may differ widely.

This conclusion is further supported by the evidence given to the Commission that prescribing physicians are primarily interested in securing the best possible therapeutic results for their patients. The loyalty of physicians to drugs they have come to know and whose effects they have found to be good, which was indicated in evidence as being a factor of some importance, while it makes the successful introduction of a new drug more difficult, also reduces the impact of price competition upon the market.

As mentioned in section 8 of Chapter XVII, the Green Book contained information about a number of antibiotics other than those already referred to in this chapter. It is of interest to observe what has happened to the prices of these products between December 1959, as shown in the Green Book, and June 1961, as contained in price lists supplied to the Commission by the companies together with the other evidence received by the Commission.

From the details contained in these sources of information it appears that between December 1959 and June 1961 the following drugs experienced the percentage reductions in list prices shown below:

Percentage Reduction

erythromycin	15.72
griseofulvin	29.17
neomycin tablets	41.08
novobiocin	15.10
triacetyloleandomycin	15.49
spiramycine	30.51

On the other hand there were no reductions in this period in the list prices of the following: cycloserine, kanamycin, neomycin sulphate powder, nystatin, ristocetin, Romicil (brand of oleandomycin), vancomycin and viomycin sulphate.

In a letter dated November 9, 1962, the Commission has been advised by Dr. L. Greenberg, Chief of the Biologics Control Laboratories, Department of National Health and Welfare, that with the exception of oleandomycin and nystatin, the drugs included in the second group are used essentially when other methods of treatment have failed. Dr. Greenberg further expressed the view that all of the drugs in this list appear to be specialties for which there has been little or no competition and which are not used to the same extent as the majority of the others.

Specific, reliable evidence of the reasons for the price reductions in the drugs in the first list has not been given to the Commission. From the details given in the Green Book (pp.177-82) it appears that in 1959 these drugs were handled only by larger, well-established companies. It further appears that these drugs were all imported, either from the United States parent of the importing company, or from England. This situation had not changed by June 1961. Three of these six products were each supplied by only one company, the others by more than one company. For those products which had more than one supplier, the prices of the suppliers in 1959 were in some cases identical and in some cases different by a few percentage points. In 1961 they were to all intents and purposes identical. For those drugs having only one supplier it seems almost certain that the price reductions in this period were the result of competitive influences, probably from other drugs, having qualities which make them acceptable substitutes in a substantial proportion of cases. Since for those drugs having more than one supplier, only from two to four suppliers were involved, the same conclusion appears to be justified, bearing in mind that in 1961 their prices were more nearly identical than in 1959.

Chloramphenicol and the tetracycline group (oxytetracycline, chlortetracycline, tetracycline and demethylchlortetracycline) are by

far the most widely sold of the broad spectrum antibiotics. The prices of almost all brands of these drugs were reduced substantially between December 1959 and June 1961, and many of them were further reduced in 1962. The spectrums of these drugs overlap those of many of the drugs we have just been discussing, and they may be used in treatment of many of the same conditions. It is therefore reasonable to assume that the price reductions in chloramphenicol and the tetracyclines were primarily responsible for the price reductions noted in respect of the other drugs.

We have still to consider what caused the price reductions in chloramphenicol and the tetracyclines. It is noted in the Green Book (p.173) that in 1959, in addition to the large brand name manufacturers there were three small suppliers of chloramphenicol, viz., Intra, Empire and Gilbert, all of whose prices were well below those of the large manufacturers. Gilbert also supplied tetracycline at a somewhat lower price and oxytetracycline at a slightly lower price than the large manufacturers. By June 1961 another small supplier, Powell, was supplying chloramphenicol, and Empire was supplying tetracycline. The evidence indicates that Gilbert was importing these drugs under their generic names at prices much below those available in North America. Empire and Powell were also generic name suppliers. The generic name suppliers were actively promoting their products at prices well below the reduced prices of the large manufacturers. It is reasonable to assume that the price reductions made by the large brand name manufacturers were not unrelated to the growing competition of low priced generic name imports.

Other influences bearing on these price reductions include improved methods of production and, in the case of Cyanamid of Canada Limited, the opening of its new plant in Welland, Ontario. Reference should also be made to the substantial price reductions in the United States by the parents of Canadian firms. The Commission has no evidence as to the cause of reductions in the United States, but it seems not unlikely that cheaper generic importations may have affected the situation. In any case, it is the opinion of the Commission that, in Canada, competition from lower priced generic drugs imported from Europe was the most important element in the price reductions made by the large brand name manufacturers.

4. Prices of Brand-named and Generic-named Drugs

It will be clear from the description of the naming of drugs given earlier in this report that drugs cannot be divided into those with brand names and those with generic names because the former will also be described by generic names where these are applicable. Nevertheless, the practice has grown up of referring to those manufacturers

who seek to promote the sale of their products by emphasizing the brand names as brand name manufacturers as distinct from those manufacturers or distributors who generally offer their products by generic name. Although there are some exceptions, the distinction is principally between the larger manufacturers who carry on research either in Canada or elsewhere, develop new products and carry out promotional activities to have such products favourably recognized by the medical and pharmaceutical professions and, on the other hand, small manufacturers or distributors who do not develop or produce the newer and more complex drugs, carry on little or no research and who do not engage in elaborate promotional campaigns.

In some of the submissions made to the Commission it was contended that the firms who distribute drugs by generic names are able to charge lower prices because they do not have to bear the costs of research undertaken by the large ethical drug manufacturers, and also because they tend to concentrate on those products which are in most active demand and on dosage forms which have the largest sale, whereas the large drug firm will continue to produce and stock products which are in very infrequent demand and to supply these at prices which do not meet the costs of such products. The brief of Cyanamid of Canada Limited makes the following comparison between the position of a manufacturer who develops new products and one who supplies well-established products:

"We could quote much lower prices on some popular antibiotic if, like the imitator, we concentrated upon existing drug forms that were the largest sellers, after the expensive promotion had already been paid for and after the drug had won the confidence of the medical profession. Cyanamid maintains a broad product line, many of the items of which have little or no commercial significance even though they may be of vital medical importance in particular cases. Examples of these are such life-saving drugs as tetanus and botulism antitoxins, on which we lose money annually. Furthermore, we maintain a countless variety of different dosage forms of the drug involved and keep our products stocked in 4,860 drug stores across the country. Most imitators do not offer this kind of variety or service. They take a few popular forms of a widely used product that has already been successfully promoted to, and accepted by, the medical profession. They do not attempt to manufacture and distribute the less popular and therefore less profitable forms. It is always possible for the imitator in any industry to under-sell the large creative manufacturer. He can sell more cheaply to institutions who buy generic name because he has no marketing operation

and no research costs. As for the much larger retail market, in order to effect sales to the public through drug stores by means of doctors' prescriptions, he has to build a marketing organization. Once he has done this, he has to make sure that he is not merely creating business for someone else. He must find a way to persuade the doctor to specify the product of his manufacture. One way is to suggest that if the doctor will prescribe by generic name, that he attach the manufacturer's name after the generic name as, for example, as seen in this plea on page 2 of the Gilbert Surgical News for May 1961, where Mr. Gilbert suggests writing the prescription under its generic name and specifying 'Gilbert'."

(Cyanamid brief, pp.29-30; Hearing, pp.1504-05)

The Gilbert firm mentioned in the above quotation is Gilbert & Company, Toronto. Mr. Jules R. Gilbert, President of the Company, appeared before the Commission and said that about 70 per cent of the sales of his company consist of dosage forms manufactured in the company's plant from basic drugs purchased in Canada or imported. Of the basic drugs used by the company, probably less than 5 per cent is manufactured in Canada (Hearing, pp.2834-36). Mr. Gilbert said that drugs which are not subject to patent rights could be purchased readily by his company in Canada or abroad but that in the case of drugs subject to patent control difficulties in acquiring supplies might be experienced (Hearing, pp.2839-41).

An example of the purchase by generic name of a drug in large demand was given to the Commission by Dr. C. S. Marshall, Administrator, Mental Health Services, Department of Public Health, Province of Nova Scotia:

"MR. MACLEOD: Do you have any experience, Doctor, in purchasing tranquilizing drugs under generic names and under brand names?

DR. MARSHALL: Yes, we had quite an experience with that. We originally purchased under brand names and then we changed from brand names to the more common and larger used drugs. Chlorpromazine, we changed from the brand name to the generic with considerable saving of money."

(Hearing, p.450)

The information on prices given in the Green Book generally shows that when drugs are sold under generic names by smaller manufacturers and distributors they are lower in price than the brand-named products of the larger manufacturers and that often the difference in price is substantial. The same situation would apply where a manufacturer sells to a hospital at a discount from list price. However, this would not necessarily be the case where a manufacturer sells to hospitals at a "net price" or when offers are made on competitive tenders at a net price.

CHAPTER XIX

PROFITS OF DRUG MANUFACTURING FIRMS IN CANADA

1. Summary of the Director's Analysis of Profits

In Chapter XIV, the Green Book gives the percentage range of profits before income tax to the value of sales for 28 listed companies whose products are principally in the ethical drug field. These figures were derived from the financial statements of the firms for the year 1959 and, in a few instances, 1958. For the 28 companies, the percentages ranged from a profit of 37.79 per cent to a loss of 1.2 per cent and the average was 17.08 per cent (Green Book, pp. 3-4, 146-47).

It should be noted that, for 9 Canadian branches or subsidiaries of firms carrying on ethical drug businesses in the United States, the average rate of profit before income taxes to sales was 15.68 per cent compared with 24.98 per cent for the parent companies in the United States. As shown in section 2 of Chapter IX of the present report, the law relating to dumping duties may, in the case of prepared dosage forms imported by a Canadian subsidiary from its parent company abroad, result in profits being taken by the parent company rather than by the subsidiary company in Canada. Such is likely to be the case when, to avoid dumping duties, the parent company charges its Canadian subsidiary a price which approaches the American trade price and thus leaves the Canadian company with a narrow margin when such imported drugs are sold in Canada (Green Book, pp. 147-48; 223-24).

For four large Canadian firms in the proprietary drug field, the percentages of profits before income tax relative to sales ranged from 20.44 per cent to 7.25 per cent and the average was 12.69 per cent (Green Book, p. 148).

The Green Book also shows calculated profit rates for 17 industrial groups compiled from Taxation Statistics, (Canada, Department of National Revenue, 1960 Taxation Statistics, Sec. III, Table 4). Pharmaceuticals appear as a sub-group under chemical products. It appears from these figures that in 1958 the rate of profit for pharmaceuticals exceeded that of any of the industry groups except paper products. At 10.5 per cent of sales, the rate of profit for pharmaceutical firms was almost double that of the average for all manufacturing industries, 5.9 per cent (Green Book, p. 151).

It should be noted in connection with the above that the rate of profit for pharmaceuticals is a rate of profit for a sub-division of an industrial group and that the comparison is made between a sub-division and a number of the larger entities. In connection with this comparison, the brief of Cyanamid of Canada Limited stated:

" . . . On page 151 of his Statement, the Director has reproduced figures from the Department of National Revenue, 1960 Taxation Statistics, for the 1958 taxation year. On this list 'pharmaceuticals' are classed as one of the divisions of the chemical industry, with a profit rate before taxes of 10.5%. Not shown in the list, however, are numerous divisions in many of the other major classifications, quite a few of which divisions show a higher profit rate than that for pharmaceuticals. Among these are the following:

(a) Food and beverages

(1) Alcoholic Beverages 16.8%

(2) Carbonic Beverages 12.6%

(b) Paper Products

(1) Pulp & Paper Mills 11.8%

(c) Non-Metallic mineral products

(1) Abrasives, Asbestos,
Cement and Clay
Products 11.2%

In addition, Primary Iron & Steel Production, a division of Iron and steel products, enjoyed a profit rate of 10.4% - only .1% less than 10.5% enjoyed by pharmaceuticals."

(Cyanamid brief, pp. 19-20;
Hearing, pp. 1488-89)

In the United States the drug manufacturing industry, a division of the chemicals and allied products industry, had a rate of profit in relation to sales which was higher than that of any of 20 industrial groups in the fourth quarter of 1958, and the first, third and fourth quarters of 1959. In the second quarter of 1959 the ratio for drug manufacturing was exceeded by that for basic chemicals. In the other quarters of 1959 and the fourth quarter of 1958, the rate of profit for basic chemicals ranked next below that of drugs (Green Book, pp. 148-49).

In the United Kingdom, the industry designated "drugs and toilet preparations" had a rate of gross profit in relation to total assets which was more than double that of all manufacturing and higher than that of eight important industries listed in the Green Book. A quotation from the United Kingdom report, Civil Appropriation Accounts, 1958-59, is given in which the opinion is expressed that pharmaceutical firms of the United Kingdom enjoyed profits in relationship to capital employed which were above those of general industry throughout the period examined, and had lately tended to increase when the rate for general industry had been falling (Green Book, p. 150).

2. Drug Manufacturers' Submissions on their Profits

Table 21 gives a percentage breakdown of the sales dollar of Canadian pharmaceutical manufacturing companies for 1958, 1959 and 1960. This material was derived from surveys conducted for the Canadian Pharmaceutical Manufacturers Association, by firms of chartered accountants and the figures were derived from replies received from 28 firms in 1958, 43 firms in 1959 and 40 firms in 1960. Table 21 also indicates between brackets the percentage figures for taxes on income and profit per dollar of sales for all manufacturing industry. The latter material, which was included in the C.Ph.M.A. brief, was drawn from a survey made by the Canadian Manufacturers' Association. As will be seen, they are substantially lower than the figures for pharmaceutical manufacturing firms.

Table 21

Percentage Breakdown of the Sales Dollar
of Canadian Pharmaceutical
Manufacturing Companies

	1958 %	1959 %	1960 %
NET SALES (That is, gross sales including sales tax where sales are made tax included, less returns and allowances):			
a. HUMAN PHARMACEUTICALS (Incl. all vitamins and over-the-counter pharmaceuticals):	80.5	73.8	84.2
b. VETERINARY PHARMACEUTICALS:	1.4	1.6	1.6
c. PROPRIETARY MEDICINES (Patent medicines but not over-the-counter pharmaceuticals):	1.0	2.9	0.7
d. CHEMICALS	3.8	7.6	5.7
e. OTHER PRODUCTS (not listed above):	12.2	12.9	6.4
f. OTHER INCOME	1.1	1.2	1.4
TOTAL	100.0	100.0	100.0
1. WAGES AND SALARIES (All wages and salaries including management salaries, directors' fees, payments to employees for holidays and in connection with profit sharing or production incentive plans, unless such payments are distributed only upon retirement of employee or some similar basis, in which case they are included in 2.):	23.7	22.8	24.3
2. EMPLOYEE BENEFITS (Payments to pension plans, group life, sickness or hospitalization insurance, workmen's compensation, unemployment insurance, medical services, cafeterias, welfare funds, 25-year clubs, etc.):	1.8	1.7	1.9

Table 21 (cont'd)

	1958 %	1959 %	1
3. MATERIALS (Including raw materials, finished and semi-finished materials purchased for resale, materials consumed in processing operations, and packaging and shipping materials, but not plant supplies which are included in 5.):	32.7	32.3	2
4. EXCISE AND SALES TAXES (Included in A above, remitted or to be remitted to Dominion and other governments):	5.1	6.0	
5. OTHER EXPENSES (Including plant supplies, power, water, municipal taxes, maintenance, repairs to buildings, machinery and equipment (not including salaries and wages or employee benefits included in 2 above), office, administrative and selling expenses not included above, including charitable and interest expense):	23.2	23.4	2
6. DEPRECIATION	1.5	1.6	
7. TAXES ON INCOME (Dominion and provincial taxes on income):	5.5 (3.6)	6.0 (4.2)	(3)
8. PROFIT (Including profits distributed and amount retained in the business):	6.5 (4.6)	6.2 (5.1)	(4)
TOTAL	100.0	100.0	10

Source: C. Ph. M. A. brief, pp. 17-19.

3. The Drug Manufacturing Industry's Justification of its Rate of Profit

Some witnesses appearing before the Commission made submissions which sought to justify the rates of profit experienced by the drug manufacturing industry in terms of the risks run by those companies. Such justifications were advanced by Mr. R.B. Thompson, Manager, Medical Products Department, Cyanamid of Canada Limited (Hearing, pp. 1484-86) and by Mr. S.N. Conder, General Manager, Canadian Pharmaceutical Manufacturers Association (Hearing, pp. 1882-84). The subject is most extensively discussed, however, in Exhibit T-10, "An Economic Analysis of the Pharmaceutical Manufacturing Industry in Canada", a study dated September 15, 1960 prepared by Dr. Brian Dixon, Consulting Economist and Assistant Professor at Queen's University:

"Risk and obsolescence - The industry is characterized by a fairly high degree of risk, in the sense that there is a continual introduction of new products, which generally operate to displace existing products. Since the rate of introduction is essentially random (due to the sporadic process of research development of new products) there is a continual risk that a new product will be cut out of the market by a better one before anything but costs have been obtained from the market.

This leads to an indicated rate of product obsolescence of a fairly high order. Yet, because the industry is characterized by an orientation to a continual stream of new products, firms must continue to bring new ones out or be prepared to lose ground competitively. This compulsion to bring out new products, with the attendant risk that the product will not pass the test of the market (either because of inappropriateness or competitive superiority), definitely gives the industry a rating of a risk industry, (as compared, let us say, to an industry which is producing a small number of relatively stable products, where the rate of product improvement or development is low). A fairly high rate of profit is to be expected under such conditions in order to induce the firms to continue to invest in what is an uncertain environment. This is not a condition peculiar to this industry, or just to the manufacturing segment of our society. High risk is expected to bring higher rewards, to compensate for the taking of the risk. That such a state of affairs is desirable appears to be eminently reasonable, not just because the greater risk justifies some extra compensation, but that it is the risk activities which tend to provide the

greatest stimulus to growth and development. It would appear desirable that such activities can expect a rate of profit higher than less dynamic ones so that investment will be channelled appropriately into activity conducive to growth. If no particularly higher rate of return was forthcoming on riskier activities it is not reasonable to expect any great willingness to perform them.

Risk in the industry is indicated in several ways. One is that the sales pattern of individual products is extremely variable year to year, and in a largely unpredictable fashion. Data on this can only be obtained from individual company examination, and is not appropriate to this analysis in any detail.

However, the obsolescence experience of one particular firm over a 10 year period gives some indication of the unpredictability (and hence risk) involved in the introduction of new products. The survey indicated that products which made up 60% of the items in the regular line, and contributed 45% of the sales volume, ceased to exist on the market at the end of the 10 year period. Such a rate of obsolescence adds substantially to the risk factor, and is a sharp example of the continued necessity for new product development and introduction if a firm is not to lose ground severely in the market.

The other statistically observable indication of risk in the industry is found in examination of the proportions of loss companies to total companies in this industry, both in the absolute, and in comparison to all manufacturing, and some other selected industries. Such an examination indicates that the proportion of loss companies has over the period 1953-58 been about comparable to that of all manufacturing, 27.2% to 27.6%, and generally higher than in industries with comparable rates of return on profit. This data supports the qualitative observation that the firms in the industry run risks by either bringing out products at a rate sufficient to assure good profits (the reward for successful risk taking) or lose out if the process is not successful (the price of failure to successfully introduce and maintain products). It would seem that it is not easy in the industry to muddle along comfortably. A firm appears to be faced with the alternative of aggressively developing and promoting its products, and enjoying financial success as a result, or being decidedly unsuccessful. Individual observation of firms in the industry bear this out, and details available as a result of hearings in the U.S. also substantiate this. All this

is characteristic of a risk industry, and in such an industry one expects and it requires a rate of return higher than the average for all manufacturing, composed as it is of industries ranging all the way from extremely high risk to virtually riskless."

(Appendix C to the C. Ph. M. A. brief,
pp. 13-15)

"PROFITS IN THE INDUSTRY

Profits in the industry have been seen to be good, but not unwarranted in view of the growth of the industry, nor in terms of the level of incentive reasonable to induce the continued high rate of capital and sales growth which has been characteristic of the industry. In addition, the rate of profit to which these comments apply, would seem to be higher than one might expect in the future, both because of indications of more difficult competitive pressures and higher costs (as will be indicated in the next section), and also because the period under analysis was a period of growth and upswing for the industry, under the impetus of the development of new drugs, and their wider application in medical treatment, as contrasted with a general stickiness of a considerable part of the period as far as the manufacturing sector of the economy as a whole was concerned."

(Appendix C to the C. Ph. M. A. brief,
pp. 37-38)

In Dr. Dixon's view, during the last ten or fifteen years there have been explosive developments in the pharmaceutical manufacturing industry which have transformed the industry from what it had been earlier. These developments have created a much more volatile industry in which many new products of different types have been introduced, a great increase in the volume of sales has occurred and innovation has led to a rapid succession of drugs replacing earlier developments. Dr. Dixon considered that under such conditions it is only to be expected that the rate of profit will be higher than for industry as a whole, particularly if trade in general is not in an expansionist period. However, there is no certainty that innovations will continue to take place at such a rapid rate in the drug industry and Dr. Dixon referred to some studies which suggest that a period may have been entered in which new drug developments will be made less frequently. If the rate of innovation does decline there will not be as rapid a rate of growth and the scale of profits is likely to decline (Hearing, pp. 2023-25).

The uncertainty created by the possible supplanting of a product made by one manufacturer with a new development made by

another was referred to by several witnesses. On this point, the following evidence was given by

(a) Mr. S.N. Conder, General Manager, C.Ph.M.A.:

"MR. MacLEOD: Page 31, Mr. Conder, you have a statement on the high degree of risk in the industry. Up to the present hasn't that been more theoretical than real? Hasn't the fact been that a greater majority of companies have been able to bring out new products, successful products? There are many examples of that. Now I suggest to you there are very few examples of a company failing or suffering substantial loss because of its product going out of fashion.

MR. CONDER: I understand, Mr. MacLeod, that there have been many examples of products which have been replaced to one degree or another over the years. That is the point on risk that is mentioned or used in our brief. . . ."

(Hearing, p. 2168)

(b) Mr. R.B. Thompson, Manager, Medical Products Department, Cyanamid of Canada Limited:

"MR. THOMPSON: . . . It is also virtually impossible to predict the useful market-life of the product and to predict over what period the capital cost of developing the product should be recovered. You may well find a competitor with a different view on the subject."

(Hearing, pp. 1704-05)

"MR. MacLEOD: You mentioned this morning, I think, that the drug industry was a very risky business. Isn't it a rather notorious fact that firms do not drop out of this business? They do not drop out of this industry? Any firm, once started, continues for years, and some of the larger firms have been going for as long as a century?

MR. THOMPSON: Oh yes, but I do not see there is an incompatibility in that situation Mr. MacLeod. The risk that I referred to is the decisions that have to be made when a new drug is available.

I can cite for you the example of a tranquilizer which my company is currently marketing. This is a new drug still. It has only been on the market a matter of a few weeks. I think it is virtually impossible to forecast just where this drug will eventually take its place in the pattern of tranquilizers.

For one thing, I have no way of knowing how the broad community of physicians will judge my drug in comparison with the many good tranquilizers on the market. I have to guess, and I have to bet money on the introduction of that drug on the basis of such a guess.

Now I might very well lose money for my company by an unwise or inaccurate decision and it is this risk to which I referred. I have the option of placing my promotional dollars in other areas where I perhaps think they would be more efficiently spent, and it is my duty to see that they are used to the very best advantage in the long range future of my company. These are constant risks."

(Hearing, pp. 1722-23)

4. Further Examination of the Industry's Profitability

The foregoing sections contain a summary of the material on the profitability of the drug manufacturing industry in Canada presented by the Director in the Green Book, and set forth the viewpoint of the drug manufacturers with respect to the profitability of their industry.

The Commission has undertaken some further study of the profitability of the pharmaceutical manufacturing industry in Canada. It is desirable that an evaluation be made of the industry's claim that the higher rate of profit it enjoys is the necessary reward for the higher risks that are run in that industry, and which result from the constant stream of new competitive products flowing from the research and development activities of the industry.

Table 22 shows the proportion of all drug manufacturing companies which suffer losses in a given year as compared with the proportion of all companies in the manufacturing sector suffering losses in the same year. This comparison is made for the years 1953-60 inclusive. As shown in Table 22, the percentage of loss companies in pharmaceutical manufacturing was on the average of the same order as the percentage of loss companies in total manufacturing.

Table 22

Loss Companies as Percentages of All Companies

	<u>Pharmaceuticals</u> (per cent)	<u>All Manufacturing</u> (per cent)
1953	25.65	27.65
1954	27.54	31.94
1955	26.05	26.95
1956	18.35	24.33
1957	30.64	26.69
1958	32.24	28.27
1959	26.32	25.94
1960	23.91	31.28
Average	26.34	27.88

Source: Department of National Revenue, Taxation Statistics, 1962, Table 2, p. 112, and the corresponding tables in issues for previous years.

A comparison of profitability of pharmaceutical manufacturing with that of all manufacturing may be made on the basis of profits in relation to sales. This comparison was made in the brief of the Canadian Pharmaceutical Manufacturers Association, which used as the basis the relationship of profit after income tax to total revenue, the latter including other revenues besides those derived from the sale of pharmaceuticals. It is desirable that the profit figure for the pharmaceutical manufacturing industry should represent the profitability of that industry alone, unobscured by earnings which may have accrued to firms in that industry from interests held by them in other industries or sectors of the economy. Therefore, earnings of the pharmaceutical manufacturing companies from bond interest, mortgage interest, dividends received from Canada and abroad, rents received and other income, should be excluded from consideration. A further adjustment is desirable in view of the consideration that a firm may raise its capital either by issuing shares, by mortgage of property or through the sale of bonds or other securities for long-term debt. The profitability of a firm which raises capital solely by issuing shares can be seen in the item, net profit for the current year, appearing in Taxation Statistics. On the other hand, a company which has raised part of its capital in the form of mortgage money or the proceeds of sales of bonds and debentures and which has sales revenues and total expenditures (except for interest on bonds and mortgages) the same as those of the company which has raised its capital solely by issuing shares, will show a smaller rate of profit owing to the payment of bond interest and mortgage interest, even though its ability to make a return on all the capital invested may be exactly the same as that of the firm relying solely on share capital. It is, therefore, desirable to add bond interest paid and mortgage interest paid to the net profit for the current year to obtain the rate of return. It is also desirable that the rate of return be measured and compared with the rate of return in all manufacturing industries before income tax, inasmuch as the rate of profitability of two companies after income tax may differ solely because of variations in the rate of income tax depending on the scale of corporate income. These adjustments have been made prior to the calculation of the rates of return on sales for both pharmaceutical manufacturing and for all manufacturing as shown in Table 23:

Table 23

Rate of Return on Sales

<u>Year</u>	<u>Profit Companies</u>		<u>Loss Companies</u>		<u>Profit and Loss Companies</u>	
	<u>Pharma- ceuticals</u>	<u>All Manu- facturing</u>	<u>Pharma- ceuticals</u>	<u>All Manu- facturing</u>	<u>Pharma- ceuticals</u>	<u>All Manu- facturing</u>
	(per cent)	(per cent)	(per cent)	(per cent)	(per cent)	(per cent)
1953	9.91	8.62	-13.33	-4.15	9.25	7.48
1954	10.40	7.73	- 8.64	-5.07	9.08	6.13
1955	11.65	8.07	-13.33	-4.59	9.96	7.59
1956	12.19	6.97	-16.18	-5.37	10.90	6.10
1957	12.67	6.90	-11.54	-6.15	10.59	5.40
1958	11.79	6.61	- 6.22	-5.28	9.88	5.09
1959	11.68	7.06	- 7.28	-4.73	10.42	5.53
1960	10.62	6.73	- 3.18	-4.39	9.24	5.28
Average	11.36	7.34	- 9.96	-4.97	9.92	6.08

Source: Department of National Revenue, Taxation Statistics.
1962, Table 4, pp. 135, 137, and corresponding
tables from issues for earlier years.

Table 23 indicates that for all of the companies in the pharmaceutical manufacturing industry (i.e. both profit and loss companies) that the rate of return in relation to sales was significantly higher than for all manufacturing in the period 1953-60. The average rate of return on sales for the period 1953-60 was 9.92 per cent for pharmaceuticals, and 6.08 per cent for all manufacturing. In other words, the average rate of return on sales in pharmaceuticals was 63.16 per cent higher than that in all manufacturing. It is also significant that, whereas the rate tended downward in all manufacturing, there is no such tendency in pharmaceuticals.

An examination of the rate of return for profit companies indicates again that the pharmaceutical manufacturing industry is considerably more profitable than all manufacturing. The average relationship for profit-making pharmaceutical companies, 11.36 per cent, was in fact 54.77 per cent higher than the average rate for profit companies in all manufacturing. Again, it is observable that whereas the rate of return in all manufacturing generally declined during this period, that in pharmaceuticals rose substantially from 1953 to 1957 and, while declining thereafter, was higher in 1960 than in 1954.

On the other hand it is observable that, among those companies which suffered losses, the average rate of loss for pharmaceutical manufacturing companies was 100.40 per cent higher than that for all manufacturing. Both groups show variations from year to year in the rate of loss but the rate for pharmaceuticals was much lower during the later years of the period than at the beginning.

The foregoing analysis also supports the view that during the years 1953-60 the pharmaceutical manufacturing industry in Canada was becoming a less risky line of business as compared with manufacturing in general. However, it is desirable to examine the return on investment in pharmaceutical manufacturing and to compare it with that in all manufacturing. It is evident that if two companies make the same rate of return on sales, but the one requires a much heavier investment of capital than the other relative to sales volume, a considerable difference results between the actual rates of return to investors in the two companies.

Return on investment has been calculated by subtracting from each year's profit, or adding to the loss, rents, bond and mortgage interest, foreign and Canadian dividends received and other revenues. As explained above, the purpose of this adjustment is to exclude earnings received from outside the pharmaceutical manufacturing industry. Conversely, bond interest and mortgage interest paid have been added to each year's profit or subtracted from the loss as shown in Taxation Statistics in order to reflect the return on all the capital which has been invested in the industry and not merely

share capital alone. The return on investment in all manufacturing has been calculated in the same way.

The capital invested in the pharmaceutical industry and in all manufacturing is arrived at from material shown in Taxation Statistics, 1962, Table 4, (pp. 135, 137) and corresponding tables of the issues of previous years by adding the items "due to shareholders", "mortgage debt", "other funded debt", "common stock", "preferred stock", and "surplus", and subtracting the item, "deficit". The rate of return on investment is, therefore, percentage relationship between the two figures calculated in the manner described.

Table 24

Return on Capital Invested

Year	Profit Companies		Loss Companies		Profit and Loss Companies	
	Pharma- ceuticals	All Manu- facturing	Pharma- ceuticals	All Manu- facturing	Pharma- ceuticals	All Manu- facturing
	(per cent)	(per cent)	(per cent)	(per cent)	(per cent)	(per cent)
1953	18.32	17.42	-10.72	- 7.89	16.62	15.03
1954	19.95	14.44	-19.90	- 9.32	17.63	11.42
1955	21.58	15.61	-31.58	- 7.55	18.73	13.69
1956	25.58	13.38	-17.19	-10.00	21.93	11.68
1957	25.03	13.41	-18.18	- 6.42	20.47	9.54
1958	23.85	11.85	-10.53	- 5.23	19.59	8.26
1959	27.25	12.90	- 9.32	- 5.07	23.05	9.25
1960	26.85	11.30	- 3.40	- 6.63	20.55	8.74
Average	23.55	13.79	-15.10	- 7.26	19.82	10.95

Source: Department of National Revenue, Taxation Statistics, 1962, Table 4, pp. 135, 137, and corresponding tables from issues for earlier years.

Table 24 shows in the main the same features and trends as were shown by Table 23. The main difference is that Table 24 makes the pharmaceutical manufacturing industry appear relatively more profitable than all manufacturing.

For the whole pharmaceutical manufacturing industry (both profit and loss companies) the rate of return on investment was on the average 81.0 per cent higher than for all manufacturing in the period 1953-60 (19.82 per cent as compared with 10.95 per cent). Again, in this period it can be seen that the return on investment of the pharma-

ceutical manufacturing industry rose by 23.65 per cent (20.55 per cent as compared with 16.62 per cent) while the return on investment of all manufacturing declined substantially (41.85 per cent).

If we look at profit companies only, a rather similar situation is shown. The average rate of return of the pharmaceutical manufacturing companies in the years 1953-60 was 70.78 per cent higher than that in all manufacturing (23.55 per cent compared with 13.79 per cent). Again, while the rate of return of all manufacturing declined (by 35.13 per cent), that of the pharmaceutical manufacturing firms increased by 46.56 per cent (26.85 per cent as compared with 18.32 per cent).

An examination of the loss companies shows that in the period 1953-60 the average negative rate of return in pharmaceuticals was 107.99 per cent higher than in all manufacturing. While both groups showed variations from year to year, these variations were much wider in pharmaceuticals than in all manufacturing. The negative rate of return in all manufacturing reached its peak of 10 per cent in 1956 and then declined to 6.63 per cent in 1960, whereas in pharmaceuticals it reached a peak of 31.58 per cent in 1955 and then declined sharply to 3.40 per cent in 1960.

These figures make it apparent that drug manufacturing gave a much higher return on capital invested than did all manufacturing and that pharmaceutical manufacturing gave an increasingly attractive return on capital invested in comparison with all manufacturing during the period 1953-60. The return on investment for profit companies was over 70 per cent better in pharmaceuticals than in all manufacturing, but at the same time the rate of loss on investment of loss companies was over twice that in all manufacturing.

These three tables taken together show that a pharmaceutical manufacturing enterprise had about the same risk of incurring a loss as a firm in all manufacturing, but that if it did so the loss was likely to be a more substantial loss either in relation to sales or in relation to capital invested than would have been the case of a company in all manufacturing. On the other hand if the pharmaceutical manufacturing firm was profitable it was likely to have a rate of return substantially higher than that for all manufacturing. To this extent the analysis of Professor Brian Dixon is confirmed.

At the same time the improved profit rates of profit companies (shown most clearly in Table 24) and the declining loss rates of loss companies in the pharmaceutical manufacturing industry suggest that it was becoming a less risky industry in itself. It contrasts in this respect with all manufacturing in which the rates of profit of profit companies declined.

CHAPTER XX

RETAIL PHARMACIES

1. Operations of Retail Drug Stores

The Green Book (pp. 65-66) presents statistics of the number of drug stores in Canada and the average number of persons per pharmacy. According to census records the number of pharmacies increased from 3,559 in 1930 to 4,325 in 1951 or by 21.5 per cent. Later census figures are not yet available but according to the Division of Narcotic Control, Department of National Health and Welfare, there were 4,924 retail pharmacies in Canada in 1961 and 4,937 in 1962. On the basis of the Department's records the increase in the number of retail pharmacies in the period 1951 - 1961 was 20.16 per cent, or almost as much as the total increase in the previous two decades.

The population of Canada has been growing at a faster rate than the number of drug stores so that the average number of persons per pharmacy has been increasing during the period for which records are available. On the basis of the figures from the Department of National Health and Welfare the average number of persons per pharmacy increased from 3,418 in 1951 to 3,505 in 1957, and has further increased to 3,704 in 1961 and 3,761 in 1962.

The average drug store usually carries a wide range of merchandise in addition to drugs and related products. Some also have soda fountains and lunch counters. Of the 4,325 drug stores reported in the census of 1951 there were 500 which were classified as drug stores with soda fountains. There are relatively few pharmacies in Canada which confine their activities exclusively to the sale of drugs and other health needs. Such pharmacies, sometimes called "ethical" drug stores or pharmacies, tend to be located in or close to medical or dental buildings.

Table IX in the Green Book (p. 71) shows that in 1951 sales of prescriptions accounted for 19.5 per cent of the total sales of drug stores without fountains while sales of other drugs, pharmaceuticals, patent medicines and compounds accounted for a further 37.7 per cent. Sales of drug sundries, rubber goods and sick room supplies constituted 6.9 per cent of drug store sales while toilet preparations, cosmetics and toilet articles accounted for 17.1 per cent.

The Canadian Pharmaceutical Association, Inc. filed with the Commission its 19th annual survey of retail pharmacy which gave the results of replies received from about 13.5 per cent of pharmacies across Canada. Reports of receipts from prescriptions were received from 413 pharmacies covering the year 1960. For the reporting pharmacies receipts from prescriptions accounted for 25.0 per cent of total receipts. The proportions varied considerably among the reporting stores as shown below:

<u>No. of Pharmacies</u>	<u>Receipts from Prescriptions as per cent of total sales</u>
149	10 to 20
148	20 to 30
80	30 to 40
36	over 40

The annual surveys of The Canadian Pharmaceutical Association, Inc. have shown receipts from prescriptions as a steadily rising proportion of the total sales of drug stores. According to estimates made by the Association on the basis of the sample survey made each year, prescription sales as a percentage of total sales of drug stores increased from 15.06 in 1951 to 26.0 per cent in 1959 (Green Book, p. 72).

Total sales of drug stores in Canada have almost doubled in the period 1951 to 1961, resulting from a larger volume of business and changes in price levels. Estimates of annual sales are given in Table V of the Green Book (p. 66) for the period 1951 to 1959 broken down between independent and chain drug stores. Figures for 1960 and 1961 and revised figures for 1959 are shown in Table 25 in comparison with those for 1951 and 1955.

Table 25

Estimated Total Sales of Drug Stores in
Canada, 1951, 1955, 1959-1961

<u>Year</u>	<u>All Drug Stores (\$'000)</u>	<u>Chain Drug Stores (\$'000)</u>	<u>Independent Drug Stores (\$'000)</u>
1951	231,816	31,019	200,797
1955	300,341	36,660	263,681
1959	405,063	53,383	351,680
1960	416,048	55,130	360,918
1961	418,488	56,464	362,024

Sources: Dominion Bureau of Statistics, Retail Trade
(annual reports) and issue of December, 1961.

The Green Book (pp. 68-70) presents data on operating results of independent and chain drug stores and certain other lines of retail trade as compiled by the Dominion Bureau of Statistics. No later figures are available for chain drug stores but figures for 1959 or 1960 have been published for independent stores and are shown in Table 26.

Table 26

Operating Results of Independent Retail
Stores, 1959 or 1960

		Gross Profit	Operating Expenses	Net Operating Profit ⁽¹⁾
		(Per	cent of Net	Sales)
Men's Clothing Stores	(1960)			
Unincorporated		28.84	19.38	9.46
Incorporated		31.47	29.97	1.50
Women's Clothing Stores	(1960)			
Unincorporated		29.92	21.82	8.10
Incorporated		32.51	30.61	1.90
Family Clothing Stores	(1960)			
Unincorporated		26.56	18.04	8.52
Incorporated		30.48	28.37	2.11
Family Shoe Stores	(1960)			
Unincorporated		30.05	19.07	10.98
Incorporated		34.08	31.07	3.01
Drug Stores	(1959)			
Unincorporated		31.58	18.88	12.70
Incorporated		32.98	29.86	3.12
Fuel Dealers	(1959)			
Unincorporated		22.44	16.84	5.60
Incorporated		23.62	20.66	2.96
Hardware Stores	(1959)			
Unincorporated		27.01	17.73	9.28
Incorporated		27.86	26.85	1.01
Furniture Stores	(1959)			
Unincorporated		27.18	18.84	8.34
Incorporated		26.30	27.08	0.78 ⁽²⁾
Appliance, Radio & TV Stores	(1959)			
Unincorporated		29.70	22.56	7.14
Incorporated (Rented Stores Only)		25.32	24.28	1.04
Jewellery Stores	(1959)			
Unincorporated		42.00	26.28	15.72
Incorporated		41.12	38.60	2.52

(1) Before income tax. Proprietors' salaries included for unincorporated stores.

(2) Operating loss.

Source: D. B. S. Operating Results and Financial Structure Reports on the various types of stores specified.

There have been relatively few failures of retail pharmacies over the years. Statistics given in the Green Book (Table XV, p.78) show that in the period 1951 to 1959 the largest number of failures among drug stores occurred in 1954 and 1955, when there were 10 in each year. However, these represented only 0.22 per cent of the total number of registered pharmacies. In 1960, 14 failures among drug stores were reported, or 0.28 per cent of the total number and in 1961, the number of failures had dropped back to 7, or 0.14 per cent of the total.

2. Profitability of Retail Pharmacies in Relation to Sales of Prescription Drugs

As has already been indicated, there is a considerable variation among drug stores in the proportions which sales of prescription drugs form of total sales. Table XII of the Green Book (p.75) is taken from the C.Ph.A. Annual Survey of Retail Pharmacy for the year 1959 and gives the operating results of reporting pharmacies according to the proportion which receipts from prescriptions form of total sales. The table shows that the rate of net profit to sales increases as the proportion of receipts from prescriptions rises. It will be noted that the rate of net profit to sales advances from 3.0 per cent in the case of stores reporting prescription sales as 10 to 20 per cent of total receipts to 8.0 per cent for those whose receipts from prescriptions formed over 40 per cent of total sales. The C.Ph.A. survey for 1960, which was filed with the Commission ⁽¹⁾, gave a similar picture with the rate of net profit to sales advancing from 3.8 per cent for the first group of stores to 7.2 per cent for stores in which prescription sales formed over 40 per cent of the total.

As shown in Table XI of the Green Book and in the C.Ph.A. survey for 1960, the operating results of retail pharmacies show a declining rate of net profits to sales from 1951 to 1955 and an upward trend from 1955 to 1957 with upward and downward movements subsequently. Over the period 1951 to 1960 there was a rise in the gross margin from 29.9 per cent to 33.8 per cent for drug stores reporting prescription sales. This appears to have occurred gradually throughout this period. Total expenses, as a percentage of net sales, increased from 23.7 per cent to 29.0 per cent so that the rate of net profit declined from 6.2 in 1951 to 4.8 per cent in 1960. Net profit, as calculated for purposes of the C.Ph.A. surveys, is the amount remaining after providing for operating expenses, including the proprietor's or manager's salary. In the case of individual

(1)

Exhibit T-16.

proprietorships or partnerships the principals' salaries would be the drawings decided upon by the owners of the businesses. Thus the net profit should be viewed in relation to the scale of proprietors' salaries. The sum of the latter and other income together with net profit is referred to in the C.Ph.A. surveys as total income which was 12.95 per cent of net sales in 1951 and 13.57 per cent in 1960. On this basis it appears that pharmacies increased in profitability during this period, the lower relationship of net operating profit to sales resulting from the proprietor's salary appropriating an increased proportion of the gross margin.

As will be seen from the footnote to Table XII of the Green Book (p.75) two series on average total income of retail pharmacies are presented in the C.Ph.A. surveys, one derived by averaging the percentage ratios calculated from the figures of the reporting firms and the other by averaging actual incomes. For the period 1951 to 1960, average proprietor's or manager's salary in relation to average total income of reporting drug stores is shown in Table 27.

Table 27

Average Proprietor's Salary and Average Total
Income of Pharmacies Reporting Prescrip-
tion Receipts

Year	Average Proprietor's or Manager's Salary	Total Income	
		Average (based on percentage ratios)	Average (based on actual incomes)
	\$	\$	\$
1951	3,652	7,880	-
1952	4,261	8,939	8,353
1953	5,725	10,121	-
1954	6,029	9,833	9,209
1955	6,467	9,914	-
1956	7,027	10,912	10,021
1957	7,400	12,574	11,419
1958	8,249	13,536	12,322
1959	8,631	14,477	13,211
1960	8,596	14,648	13,550

Sources: C.Ph.A. Annual Survey of Retail Pharmacy,
Canadian Pharmaceutical Journal, various issues.

3. The Function of the Retail Pharmacist

The Green Book (para. 52, p. 26) states that at least 85 per cent of all ethical drugs dispensed by pharmacies are compounded at the manufacturer's level. It is interesting to compare this estimate with the results of two surveys about which detailed information will be given in Chapter XXII: one conducted by The Alberta Pharmaceutical Association and the other by Dean F.N. Hughes and Professor G.C. Walker. According to these respective surveys only 3.96 per cent (see Table 31) and 5 per cent (see Table 32) of all prescriptions were extemporaneously compounded by pharmacists.

The changing role of the pharmacist as he becomes more a dispenser of drugs in dosage forms prepared by the manufacturer and less a dispenser of prescriptions compounded by himself was often referred to in the course of the hearings. The following comment on this development is contained in the brief of The Canadian Pharmaceutical Association, Inc.:

" . . . In practice, pharmacy techniques have become less important, while Pharmacy's knowledge of medicinals, their uses, contraindications, dosages and toxicity have become increasingly vital. . . ."

(Association brief, p. 80;
Hearing, p. 2517)

The brief gives a detailed description of the steps and procedures required of a pharmacist in the dispensing of a prescription under the following heads:

1. Identification of validity and legality of prescription.
2. Identification of physician and patient.
3. Deciphering the prescription.
4. Checking the dosage.
5. Determination of quantity.
6. Assembling the ingredients.
7. Filling the prescription.
8. Choice of container.
9. Preparation of the label (including special instructions on label when required).

10. Register entry.
11. Prescription notations for future reference.
12. Double checking of entire process.
13. Provision of income tax receipt to customer.
14. Filing prescription.
15. Delivery of prescription to customer, including verbal instructions.

(Association brief, pp.76-79)

The brief of The Canadian Pharmaceutical Association, Inc. indicates the many ways in which the retail pharmacist acts as a health consultant in his community and provides many services, such as answering emergency calls outside normal business hours, stocking vaccines for public health programmes, carrying drugs in little demand, etc., which do not yield a commensurate monetary return. Although the druggist is not qualified to diagnose illness or to prescribe, he may be asked by customers to give advice on the relative merits of a group of products for the treatment of self-diagnosed minor ailments, and the public has come to expect an unbiased recommendation of specific products from the pharmacist (Association brief, p. 63; Hearing, pp. 2472-74).

While stressing the continuing importance of the professional services rendered by the retail pharmacist the brief of The Canadian Pharmaceutical Association, Inc. admitted that the diversity of interests involved in the operation of a drug store as a commercial enterprise led to conflict with the professional aspects of pharmacy:

"Pharmacy is an ancient profession. The fact that it is customarily practised as a part of a retail business establishment has brought about certain conflicts between scientific requirements, professional ethics, and the desire -- in fact, the need -- to make a profit.

Seen in its entirety, pharmacy is a conglomeration of diverse interests. In particular, the interests of the pharmacist as a profit-seeking retailer and the pharmacist as a professional technician are frequently in conflict. From the beginning of Canadian pharmacy the pharmacist -- or druggist, as he was more commonly known -- has engaged in merchandising of a variety of related commodities. There is no question that the manifold merchandising activities in which most pharmacists engage today are honourable and that the function of distribution is as important as any other in the economy of our society. As a con-

sequence, and because only in a minority of businesses has commerce in medicinals been sufficient for the successful maintenance of a strictly professional pharmacy, the drug store has evolved, under the conditions of a free enterprise economy, to its present stage. In modern times, the range of its commercial undertakings has been extended within variable limits but with a concurrent effort to always provide necessary professional service to its community."

(Association brief, p. 55;
Hearing, p. 2442)

Retail pharmacy thus occupies a unique position in retail trade in Canada in its combination of merchandising activities and professional dispensing. In so far as the dispensing of ethical pharmaceuticals is concerned, the retail druggist is not engaged in merchandising as this activity is generally carried on in retail stores. The practice of mass merchandising which has become a dominant factor in many lines of retail trade plays no part in the supplying of ethical drugs, each one of which is dispensed in accordance with the specific prescription of a physician for an individual patient.

Provincial laws normally require that the dispensing of drugs be conducted by a registered pharmacist. As to the ownership of retail pharmacies, it may be held either by a registered pharmacist or by a corporation, but in some provinces⁽¹⁾ no corporation may operate a pharmacy unless the majority of the common stock is owned by and registered in the names of licensed pharmacists and/or unless the majority of its directors are registered as pharmacists. The brief of The Canadian Pharmaceutical Association, Inc. stated that from the retail viewpoint pharmacy is not in the class of big business and referred to the fact that approximately 90 per cent of the 4,900 drug stores in Canada are, generally speaking, individually owned and operated. According to the Association's brief there are 39 companies operating chains of drug stores which embrace about 431 stores (Association brief, p. 56; Hearing, pp. 2445-46). The Dominion Bureau of Statistics estimated that in 1951 independent stores accounted for 79.2 per cent of the sales of drugs and drug sundries while chain stores accounted for 11.8 per cent and department stores for 9.0 per cent⁽²⁾. The commodity class, "drugs and drug sundries", embraces a much wider range of products than ethical drugs.

(1) See e.g. Statutes of Nova Scotia, 1962, c.11, s.24; Revised Statutes of Ontario, 1960, c. 295, s. 34; Statutes of Saskatchewan, 1954, c.74, s.55; Statutes of British Columbia, 1960, c. 282, s. 29.

(2) Restrictive Trade Practices Commission, Report on an Inquiry into Loss-Leader Selling, Ottawa, 1955, p. 191.

It was the opinion of practising pharmacists who appeared before the Commission and the same view was presented by The Canadian Pharmaceutical Association, Inc. (Association brief, p. 65; Hearing, p. 2479), that the individual druggist is in no bargaining position, vis-a-vis the manufacturer, in his purchase of drugs and pharmaceuticals but must pay the prices set by suppliers. Not only is the typical drug store a neighbourhood centre under individual ownership and thus without any concentrated buying power, but, at least for prescription drugs, the products themselves are individually requisitioned by buyers on prescription and thus are not in any way comparable with products which are mass merchandised. It is true that there are a few large retail drug companies and that in Ontario, for example, retail druggists have a co-operative buying agency, Drug Trading Co-operative Limited, which does a large volume of business. Such an agency, in other lines of retail trade, might have a stronger bargaining position than that of an individual retailer in dealing with manufacturers but its position is not much different in obtaining supplies of ethical drugs. This is due to the fact that such products, for the retail drug trade, are packaged to meet the anticipated needs of individual patients and are ordered as such needs arise. The opportunities which exist in other lines of trade to create demand through advertising to the public and to buy in large quantities at favourable prices to satisfy such demands do not exist in the distribution of prescription drugs.

4. Increase in Sales of Prescription Drugs

The increasing proportion which sales of prescription drugs form of the total sales of drug stores is a reflection of the growth in the number of prescriptions filled and the increase in the average price per prescription. The Green Book (p. 72) presents statistics for the years 1951 - 1959 inclusive, on the total number and total value of prescriptions dispensed by Canadian pharmacies, together with the average price per prescription and the proportion which receipts from prescriptions form of the total sales of drug stores. These statistics were derived from surveys made by The Canadian Pharmaceutical Association, Inc. and published in the Canadian Pharmaceutical Journal. Similar statistics for 1960 and 1961 have been published and are shown in Table 28 together with comparative figures for 1951 and 1955.

Table 28

Number and Value of Prescriptions
1951, 1955, 1959, 1960 and 1961

<u>Year</u>	<u>Number of Prescriptions</u>	<u>Value of Prescriptions</u> \$	<u>Average Price of a Prescription</u> \$	<u>Prescription S as % of Total S of Drug Stor</u>
1951	30,958,675	52,010,574	1.68	15.06
1955	32,908,185	74,372,498	2.26	19.96
1959	43,916,605	130,871,483	2.98	26.0
1960	42,840,810	131,092,880	3.06	25.0
1961	42,540,814	133,578,157	3.14	25.7

In the period 1951 - 1961 the population of Canada increased by 30.19 per cent but, as shown by Table 28, the number of prescriptions increased by 37.41 per cent and the average price per prescription by 86.9 per cent. Various explanations were given to the Commission to account for the marked rise in the sales of prescription drugs.

It may first be noted that the increase in the demand for prescription drugs during the past decade occurred during a period when the income and standard of living of Canadian families were, on the whole, increasing rapidly so that increased expenditures on health requirements, including prescription drugs, would form a part of the conditions for a higher standard of welfare. The increased coverage of medical and hospital insurance schemes must also be considered as a part of improved living conditions and they have undoubtedly contributed to the increase in the use of prescription drugs.

In the brief of The Canadian Pharmaceutical Association, Inc. the following factors were also mentioned as having important roles in the increased use of prescription drugs: the growing urbanization of the Canadian population, changes in the age composition of the population, the increasing reliance on drugs concomitant with greater confidence in their therapeutic efficacy and the rising ratio of physicians to population (Association brief, pp.85-89).

On the basis of estimates of the average expenditures on prescriptions for the population as a whole and for urban families, The Canadian Pharmaceutical Association, Inc. concluded that the latter spend more on prescription drugs than rural families. Consequently, prescription sales would tend to increase as the proportion of urban dwellers grows. As city residents usually have more ready access to both medical and pharmaceutical services it would be expected that their expenditures in these directions would tend to be greater, on the average, than those of persons residing in rural areas.

During the past decade the proportions of children and of elderly persons have been increasing. The C.Ph.A. brief pointed out that new medications have played a large role in decreasing infant mortality and in increasing the life span. The growing size of these two groups would lead to larger demands for prescription drugs.

The brief presented to the Commission by the Government of Saskatchewan contained statistics of expenditures for drugs and appliances under provincial health schemes, applying to beneficiaries of old age pensions, mothers' allowances and blindness allowances. These statistics reveal a great increase in the average expenditures per beneficiary in the period 1949-1950 to 1958-1959, as shown in Table 29.

Table 29

Average Expenditures per Beneficiary for Drugs
and Appliances, Saskatchewan, Fiscal Years,
1949-50 and 1958-59

	<u>Old Age Pension</u>	<u>Mothers' Allowance</u>	<u>Blindness Allowance</u>
1949-50	\$6.24	\$2.67	\$5.86
1958-59	20.51	7.42	13.32

Source: Submission of the Government of Saskatchewan.

The C.Ph.A. brief cited figures which showed that, between 1956 and 1960, the number of doctors practising in Canada increased at a faster rate than the population as a whole, so that the number of persons per physician declined from 970.4 in 1956 to 881.9 in 1960. The fact that physician's services are more readily accessible to the population would tend to increase the number of prescriptions received by the population (C.Ph.A. brief, p. 88; Hearing, pp. 2533-34).

A further factor mentioned in the C.Ph.A. brief and the one which would appear to have played the major role in the increased demand for prescription drugs has been the great development of new remedies providing a wide range of treatment. The brief cited an estimate that 45 per cent of the drugs now prescribed were not available to physicians five years ago.

It would appear to be this factor which has been mainly responsible for the large increase in the annual per capita expenditures on prescription drugs which have advanced from \$3.71 in 1951 to \$7.36 in 1960 (C.Ph.A. brief, p. 85; Hearing, p. 2529). In the C.Ph.A. brief various calculations were presented attempting to show what the trend in per capita expenditures has been in terms of constant dollars or some other measure to remove the inflationary movements of the past decade. Actually, however, the price index for prescriptions as compiled by the Dominion Bureau of Statistics has not followed the general cost of living index as it stood at 106.1 in 1951, 111.6 in 1959, 112.9 in 1960 and 100.6 in 1961. The increase in per capita expenditure on prescription drugs, therefore, cannot be attributed in any large degree to increases in the prices of the same group of drugs but must be accounted for by greater use of higher-priced drugs of newer types and, perhaps, larger quantities per prescription.

5. Question of Subsidization of the Dispensary in Retail Drug Stores

The argument was advanced by The Canadian Pharmaceutical Association, Inc. that prescription services rendered by many community pharmacies having a low volume of prescription business must be subsidized by other sales income. The Commission does not believe that this argument correctly presents the situation where a professional pharmacist spends a large part of his time selling non-drug lines of merchandise and only a minor part of his time in dispensing prescriptions. In such a case, the pharmacist retailer derives a larger part of his income from the sales of other goods than would be the case if his volume of prescription business was larger, but it does not necessarily mean that he derives no profit from the sale of prescription drugs. It might still be the case that such sales constitute the most profitable phase of his operations, even though, if he had to rely entirely on them, he would not be able to continue in business. The sales of other lines of goods in circumstances where only a low volume of prescription sales is obtainable permit the operation of a dispensary but the same conditions exist with the many lines handled by a drug store, no one of which could be distributed as the exclusive business of the store.

Another argument advanced by The Canadian Pharmaceutical Association, Inc. was that a large proportion of prescriptions (estimated in one locality at 46 per cent) is supplied at a loss because the prescription price is below the "average breakeven cost" of dispensing which, in the example, was given as \$1.72. While there may be some question as to the validity of the cost elements used in arriving at the breakeven cost in that they include a single hourly charge for the pharmacist's services and an average time for filling a prescription, there is a more serious weakness in the argument.

As has already been pointed out the operation of a drug store involves joint costs in the distribution of a variety of merchandise. The same is true of the operation of the dispensary and the fact that a substantial proportion of prescriptions is relatively low-priced does not mean necessarily that such prescriptions are sold at a loss. Unless the pharmacist could be fully occupied in dispensing higher priced prescriptions or in selling more profitable lines of merchandise the dispensing of lower priced drugs will make a contribution to the income from the dispensary and thus increase the total income of the business and the profits of the proprietor.

6. Large Volume Dispensing of Prescriptions as a Means of Reducing Prices

During the inquiry question was raised whether there could be changes in the organization of the retail drug trade, particularly in metropolitan areas, toward greater specialization in the dispensing of prescriptions which would result in savings for the buyers of prescription drugs. The following questions were posed in the brief of the Government of Manitoba:

"What changes in the structure of the retail drug trade would promote more economical methods of distribution to the public?

Does the endorsement of pricing schedules by the Provincial Pharmaceutical Association tend to hinder the development of the larger pure dispensaries with an associated possible price saving to the consumer, and does it foster the continuation of the small community outlet with its relatively higher cost of operation?"

(Government of Manitoba brief, p. 6;
Hearing, pp. 576-77)

These and similar questions were discussed with witnesses representing retail pharmacists who did not feel that any significant savings could be made in the cost of distributing prescription drugs through changes in the structure of the retail drug trade, or that the public desired any changes in the present system. Mr. Richardson of The Manitoba Pharmaceutical Association said that in a metropolitan area some saving might be possible if dispensing was concentrated in larger dispensaries, but most customers want the service which is provided by the community drug store (Hearing, pp. 632-33). Mr. Pepper of The Saskatchewan Pharmaceutical Association expressed somewhat the same opinion and pointed out that in 160 communities in Saskatchewan there is only one drug store and that it could not be maintained if other goods were not sold (Hearing, pp. 822-23, 826-27).

In the submission made on behalf of The Canadian Pharmaceutical Association, Inc. the position was taken that a large volume of prescription sales does not provide an opportunity for distribution at lower prices than in a drug store with a small volume. It was contended that expenses as a percentage of sales tended to increase as the volume of prescription business increased and thus there would be no saving which could be passed on to the consumer (Association brief, pp. 93-94; Hearing, pp. 2547-49). While the figures compiled in the C.Ph.A. surveys show higher expense ratios for the drug stores having the largest volume of prescription sales (see Table XII of the Green Book) they also show that a significant part of the increase is accounted for by proprietor's or manager's salary. More significantly, the statistics show that the drug stores with the highest volume of prescription sales have a much larger gross margin than the stores with the lowest volume of prescription sales. This difference would appear to be related to the terms on which the respective groups of stores purchase their supplies of prescription drugs. The Canadian Pharmaceutical Association included in its brief the results of a survey which it conducted in all provinces except Newfoundland of the prices at which eight specific drug and sundry items could be purchased from manufacturers and wholesalers. It was found that the maximum difference in cost prices, expressed as a percentage of the lowest price, was 83.3 per cent. There was as much as 50 per cent variation in prices paid for different purchases from a manufacturer and up to 39.2 per cent variation in price on purchases from a wholesaler (Association brief, pp. 100-101, 103; Hearing, pp. 2576-77).

The general practice among retail pharmacists of following the manufacturer's retail list prices in charging for prescription drugs when such wide variations occur in the cost of such drugs to retailers buying in different quantities or from different sources would thus appear to impede the development of distribution methods which would provide savings to consumers. The adoption of more flexible methods of pricing by individual druggists seeking to build up their prescription business and allowing economies in purchasing and dispensing to be reflected in lower prices to consumers would seem to offer possibilities for savings by drug users, particularly in large urban centres.

7. Concern over the Supply of Pharmacists

Concern was expressed to the Commission by representatives of associations of pharmacists and by members of the faculties of schools of pharmacy over what was stated to be the growing scarcity of graduate pharmacists in relation to the demands for pharmacists. Following an increase in the enrolment of students in schools of pharmacy in the immediate post-war period there was a decline in students entering such schools which seems to have persisted until 1957. Since then enrolment of pharmacy students has increased from 1109 in 1957 to 1482 in 1960. The number of students graduating from schools of pharmacy generally declined until 1955 when there were 261 graduates and since then, with reversals in some years, the trend has been upward. Figures secured from the Dominion Bureau of Statistics give 263 graduates in pharmacy in 1960, of which 57 were women and 281 in 1961, including 86 women. In some provinces schools of pharmacy have had more applicants than could be enrolled with the facilities available but this limitation is in the course of being removed as greater facilities are being provided to permit the acceptance of more applicants seeking to study pharmacy.

In addition to the growing number of retail pharmacies in Canada requiring the services of registered pharmacists, witnesses referred to the growing demands for pharmacists in a number of other fields. Pharmacists are sought by industry both as detail men and also in production and laboratory work. Reference was also made to the increasing demands for pharmacists in hospitals and by various governmental departments as well as the armed forces. In an effort to stimulate the interest of students in taking up pharmacy as a career the professional associations have given increased attention to vocational guidance and student recruitment which, it is thought, may have assisted in the larger enrolment in schools of pharmacy in recent years (C.Ph.A. brief, p. 19; Hearing, pp. 2332-33). Fears were expressed that in spite of the efforts to secure a larger number of graduate pharmacists there would be a growing shortage of pharmacists in relation to the demand for persons with such training. No definite views were expressed as to what effects a continuing shortage might produce in the retail drug field although Mr. P.T. Moisley, Registrar-Treasurer, The Ontario College of Pharmacy, said that he had noticed a tendency in Toronto for druggists operating a small pharmacy to close it and enter into partnership in a large business. Such a development, of course, does not lessen the employment of pharmacists but if an actual shortage of pharmacists to operate retail dispensaries develops there might well be a trend toward larger dispensaries engaged exclusively in handling drugs and related products in which pharmacists would devote their full time to dispensing drugs.

CHAPTER XXI

RETAIL PRICING OF DRUGS

1. Adherence of Retail Druggists to Manufacturers' List Prices

The general situation in Canada with respect to the retail pricing of drugs sold on prescription is described fairly fully in Chapter IX of the Green Book. Witnesses before the Commission generally agreed with the Director's description of pricing practices of druggists in the various provinces as being factually correct, but some stated that price variations among drug stores in the same community were more common than the Green Book would suggest. Information received by the Commission related largely to the way methods of pricing were followed in different areas. The manufacturer's list price or suggested resale price is used as a basis of pricing by retail druggists almost without exception. During the hearings the Commission was informed of one or two druggists in some of the provinces who used other methods of pricing, but such instances were clearly regarded as exceptions. In order to arrive at the price to be charged on the filling of a prescription there is added to the manufacturer's list price a prescription fee which is generally established by the use of a formula. Various formulas are described in the Green Book. Some of them are recommended by provincial associations of druggists, others are of a local nature or are prepared by commercial agencies. The following comments on the use of such pricing guides are contained in a report of a joint committee consisting of representatives of the Government of Manitoba and The Manitoba Pharmaceutical Association:

"In Manitoba, as in most of the other provinces of Canada, it is the practice for the majority of retail pharmacists to use a standard pricing guide or formula to calculate retail prices of prescriptions. There are at present separate guides being used in most of the provinces. These guides are prepared by agencies of the provincial pharmaceutical associations or by private organizations with the approval of the provincial pharmaceutical associations. Although complete data is not available, there are indications that about 80% - 85% of all retail pharmacists in most provinces use the pricing guide which is endorsed by the local pharmaceutical association".

(Annex No. 3 to The Manitoba
Pharmaceutical Association brief, p. 42)

The heavy responsibility of the pharmacist in compounding or filling prescriptions and other considerations which lead to the charging of a fee, in addition to the price of the drugs, are described in the Green Book (p. 104). The following comments on the professional aspects of the pharmacist's activities were made in the brief of The Canadian Pharmaceutical Association, Inc.:

" . . . Basically, the pharmacy practitioner is a specialist in the science of drugs and in this capacity stands as one of the guardians of the health of his community where he practises. Few modern prescriptions require the exercising of the ancient art of the apothecary, but they do demand much more of a pharmacist's scientific knowledge respecting the medicines prescribed. He is the custodian of poisons and the specialist in the science of drugs, responsible for the quality and the integrity of the drugs which he dispenses, and sharing responsibility if harm ensues from prescribed overdoses. His training is such that, by law, he is expected to protect equally the physician and the patient.

Pharmaceutical service, today, implies the assumption by the pharmacist of a heavy professional responsibility in the utilization of the basic scientific knowledge which he possesses. The rendering of pharmaceutical service is not a mere expansion of a simple commercial transaction which requires nothing more than the ability to correctly read labels and transfer medications."

(Association brief, p. 14;
Hearing, pp. 2320-21)

While the policy of using the manufacturer's list price in determining the amount to be charged on a prescription is almost universally followed, there may be variations in the amount of the professional fee arising out of the use of different formulas or of the policy in charging the fee. Mr. W. Isaacson, a member of the Council of The Ontario College of Pharmacy and a proprietor of retail pharmacies in Toronto, gave the following evidence in regard to the charging of a dispensing or prescription fee:

"MR. ISAACSON: Well now, that varies again. As I say, we take a lot of leeway in those high priced drugs. I believe I could say every pharmacy does and if I felt that \$7.90 was enough I would not even charge a 75¢ fee. I would not say that it would be [the] same in every case, but where I feel, in my judgment I don't want to take the fee, I would just charge \$7.90.

THE CHAIRMAN: You mean your price for the same prescription might vary as between customers?

MR. ISAACSON: Well, it would become a policy of the store for a high priced drug not to add on the fee.

THE CHAIRMAN: Is that your policy on high priced drugs?

MR. ISAACSON: I don't want to be pinned down that it would be in every single case, but usually."

(Hearing, p. 2967)

The brief of The Alberta Pharmaceutical Association made the following comments on pricing methods in that province:

"There is another school of thought in Alberta which advocates the dispensing at cost plus a professional fee. The fee most usually quoted is \$2.00. This method has not, to the Association's knowledge, had a sufficiently widespread trial to estimate its worth in this Province.

Prescription pricing runs the entire gamut of these various methods in Alberta, i. e. dispensing at suggested list plus a professional fee of \$.75 or \$1.00, dispensing at list, and dispensing at cost plus a professional fee, or an individual store policy that is a variation of one or more of these.

(Association brief, pp. 7-8;
Hearing, p. 1014)

Mr. Alfred Pepper, President of The Saskatchewan Pharmaceutical Association, told the Commission that in Saskatchewan it has become a common practice not to charge a professional fee when dispensing drugs in higher price ranges in unbroken packages (Hearing, pp. 807-08). The reason for charging only the list price for the more costly drugs is explained by the way in which the discount system operates. As has been pointed out previously, the same discount from list price is usually allowed by a manufacturer regardless of the cost of a drug. In the case of the usual discount of 40 per cent, a druggist buying a drug from a manufacturer which has a list price of \$1.00 will have a margin of 40 cents. On a drug which has a list price of \$8.00 the gross margin will be \$3.20. It should be kept in mind that large quantities of drugs are distributed through wholesalers and that on purchases from such a source the retail druggist will usually not receive as large a discount as he would on direct purchases from the manufacturer. On the other hand, the druggist may receive a quantity discount or other allowance by purchasing a "deal". Such special allowances, however, are usually given with non-prescription drugs. Nevertheless, regardless of the particular terms of purchase, the manufacturer's list price is still considered the basis for determining the price to be charged to the consumer. The Green Book points

out that although druggists adhere almost without exception to the use of manufacturers' list prices, there is no evidence that drug manufacturers attempt to force retailers to maintain prices. The practice of resale price maintenance has been forbidden under the Combines Investigation Act since 1951.

2. Attitude of Associations of Pharmacists toward
Advertised Price Reductions

Variations in the price of the same drug at different drug stores in the same city, as the result of differing policies in charging a professional fee or for other reasons, do not appear generally to give rise to active concern on the part of druggists' groups or associations unless the possibility of lower prices is brought to the attention of the public through some form of advertising. At the same time it is probable that the interest of provincial pharmaceutical associations in preparing and issuing price guides is due, in some measure, to a desire to lessen the amount of price variations among drug stores.

The pharmacy acts in several provinces provide for the adoption of a code of professional conduct which becomes binding on druggists practising in the province. The Commission was informed that a provincial code has not been adopted in British Columbia but codes in force in several other provinces were brought to the attention of the Commission.

The Ontario College of Pharmacy's "Code of Professional Conduct" contains the following provisions relating to advertising:

"10. He should not advertise in any way that suggests or implies that any other pharmacist does not observe or adhere to the best Pharmaceutical Standards.

. . .

12. The pharmacist should endeavour to publicize and promote professional services and the value of pharmacy to the public. His displays, interior and exterior, should be of a character which will enhance public confidence in his professional integrity.

13. The pharmacist should not lend his support or his name to the promotion or exploitation of objectionable or unworthy products, nor should he participate in any advertising or promotional programme which would tend to lower the honour and dignity of the profession.

27. The pharmacist should not in any advertising make any reference to price for compounding and/or dispensing of prescriptions.

28. The pharmacist should not deliberately underprice a prescription or a copy for the purpose of injuring the reputation for fair dealing of other pharmacists."

(Exhibit T-24)

The "Code of Ethics" of The Manitoba Pharmaceutical Association contains somewhat similar provisions, including the following:

"3(e) A pharmacist shall not in any advertising nor in any solicitations to a prescriber or group of prescribers make any reference to price for compounding and/or dispensing of prescriptions or for any drugs or medicinals that may be used in prescriptions."

(Annex No. 2 to The Manitoba
Pharmaceutical Association brief,
pp. 2-3)

Some examples were cited to the Commission of the manner in which the above provision would be regarded by The Manitoba Pharmaceutical Association but the examples were, in fact, hypothetical. It was stated that the giving of premiums in connection with the sale of prescription drugs would be regarded as unethical as would the advertising of the best price on generic drugs without establishing the quality of the product (Hearing, pp. 639-45).

The Commission was not informed of the existence of a code of ethics relating to the practice of pharmacy in the Province of Saskatchewan. Mr. Alfred Pepper was asked what attitude would be taken in regard to price cutting in the drug field:

"MR. MacLEOD: Do you feel that price cutting in the drug field is improper? Let me put it another way. Do you feel that to approach the public on the basis of better prices is improper?"

MR. PEPPER: No. I think that has been standard for many, many years, one of the standard business-getters.

MR. MacLEOD: Is that applicable to the drug trade?

MR. PEPPER: Are you speaking of prescriptions now?

MR. MacLEOD: Prescriptions.

MR. PEPPER: I don't think it is. This is just a personal opinion. It suggests that perhaps there may not be proper care given; that some place there has to be a corner cut to reduce the price considerably."

(Hearing, p. 816)

Mr. Douglas Denholm, Registrar of The Pharmaceutical Association of the Province of British Columbia, informed the Commission that his Association had never taken any stand concerning the prices for prescription drugs charged by Association members, nor did it take any action if one or more members complained about the prices charged by another (Hearing, pp. 1243-44).

3. Coding of Prices on Prescriptions

The Commission heard some evidence on the practice of coding prescriptions. This is the practice of the druggist putting a code designation on a prescription to indicate the price at which it had been or would be filled. If the practice is followed and the coded prescription is presented to another druggist he would be informed of the price which had been placed on the prescription by the first druggist. The Commission did not receive any evidence which would indicate that a druggist presented with a coded prescription would feel that he is bound to charge the same price but it is reasonable to assume that the practice would tend to encourage the adoption of the price which had been coded.

Some dispensing fee schedules issued by pharmaceutical associations recommend or even require the practice of coding prescriptions. The following appears in the "Dispensing Fee Schedule (Suggested for Guidance)" of The Manitoba Pharmaceutical Association:

- "6. The practice of coding prices on all copies of prescriptions to patients should be followed (even if only a price is asked for on new prescriptions)."

(Annex No. 4 to The Manitoba
Pharmaceutical Association brief)

In Alberta, paragraph 6 of "General Instructions" under The Alberta Pharmaceutical Association Professional Prescription Fee Schedule reads as follows:

"6. All copies of prescriptions and new prescriptions on which prices have been quoted must be coded (N.A.R.D.)".

(Exhibit C-1)

The tendency to follow the coded price is probably strengthened by the following provision of the "Code of Ethics" of The Manitoba Pharmaceutical Association, which is very similar to the already quoted section 28 of The Ontario College of Pharmacy's "Code of Professional Conduct":

"3(f) A pharmacist shall not deliberately under-price a prescription or a copy for the purpose of injuring the reputation for fair dealing of other pharmacists."

The evidence before the Commission indicates that the practice of coding is followed by the majority of pharmacists, but not by all.

4. General Situation with Respect to Pricing of Prescriptions

The general effect of the practices followed by retail pharmacists in pricing prescriptions is to produce uniform or closely similar prices for comparable prescriptions in the same area. Variations in prices are not excluded but they will not significantly affect the prevailing pattern of prices.

Mr. Alfred Pepper gave the following examples of price variations which were found in a quick survey:

"MR. MacLEOD: Do you know whether your members adhere very closely to that professional fee?

MR. PEPPER: Not very closely, no. We attempted to find out in a very quick survey this last week, and asked prices on five different items in 23 different stores, and in the case of a compounded item, I think the answer was 12 different prices, or 14 different prices, ranging from \$2.00 to \$3.00 on a bottled prescription. On the ready-made products, on a tablet from 22 stores there were 8 different prices, from \$3.50 to \$3.80."

(Hearing, pp. 806-07)

Mr. W. Isaacson, a druggist in Toronto, said that while competition in price with respect to prescription drugs would not be

significant in high income suburban areas, it was more intense in other sections of the city (Hearing, p. 2982).

The general attitude of retail druggists toward the competitive pricing of prescriptions, particularly in a manner which draws public attention to the competition, appears to be that such activity does not conform to the standards of professional conduct which should prevail in pharmacy. At the same time consideration is being given by individual druggists and by groups of pharmacists to other methods of pricing prescriptions, such as cost of ingredients plus a dispensing fee. It was suggested to the Commission that in some circumstances such a method might increase the price to the consumer of prescriptions calling for ingredients of relatively low cost, and decrease the price of more costly drugs.

5. Incidence on the Pricing of Drugs of Governmental
Programmes of Assistance to Certain
Population Groups

The Green Book (paragraphs 159-60, pp. 92-93) deals with the supplying of hospital patients with drugs and the manner in which hospitals recoup the cost of these drugs.

Drugs are provided free or on an assisted basis to certain population groups by some at least of the provincial governments and by the Federal Government. However, as assistance by the Federal Government in this field was not the subject of evidence given to the Commission no review of its nature is attempted in this report. In the case of provincial programmes the Commission has not undertaken an exhaustive enumeration of such assistance schemes. Those which are considered in the following pages may not constitute all the programmes of aid which are in effect.

Information received by the Commission relates principally to the programmes for the free or assisted provision of drugs in force in Alberta, British Columbia, Saskatchewan and Manitoba.

The following features were mentioned in connection with the programme of assistance provided to certain classes of drug consumers by the Government of Alberta. As is the case in most provinces, all necessary drugs prescribed in hospitals in Alberta by hospital staffs are provided and the cost is borne by the taxpayer. This applies only to hospital prescriptions, not to private ones (Hearing, p. 868). Those old age pensioners in Alberta who are in receipt of additional pensions from the Alberta Government receive free hospital care and free drugs while they are inside the hospital, but outside the hospital they have to pay for their drugs themselves (Hearing, p. 871).

The Alberta Government provides insulin to diabetics on a modified form of means test. Tolbutamides for diabetics are provided free (Hearing, pp. 884-85, 890). Penicillin for the prophylaxis of streptococcal throats in the prevention of recurrent attacks of rheumatic fever is provided free by the Alberta Government (Hearing, pp. 886-87, 890).

In the Province of Manitoba, recipients of social allowance are provided with what is commonly called a Medicare Certificate, which they can take to a physician of their choice. If he prescribes drugs, the prescription may be taken to any one of four hospital pharmacies in Greater Winnipeg or to a retail pharmacist, and filled at no cost to the patient. Outside of Winnipeg prescriptions are taken only to retail pharmacists. In the case of prescriptions filled at hospital pharmacies the Government of Manitoba is billed at the direct cost to the hospital which includes 40 cents to cover administration costs. In the case of prescriptions filled by retail pharmacists the Government has an agreement with The Manitoba Pharmaceutical Association under which such prescriptions are priced at the manufacturer's list price less 15 per cent, plus a dispensing fee (Hearing, pp. 595-97). During the first nine months of the Medicare Program some 26,550 prescriptions were dispensed under the plan through retail outlets in rural areas at an average cost of \$2.82 per prescription. The average cost in the City of Winnipeg for 13,659 prescriptions was \$3.03. For 2,479 prescriptions dispensed through hospital pharmacies the average cost was \$1.65 (\$1.25 basic cost plus 40 cents administration charge) (Hearing, pp. 572-). It was explained that the 40 cents administration charge was made to cover primarily the salary of the dispensing pharmacist in the hospital and did not contribute to other costs involved in operating a hospital pharmacy (Hearing, pp. 601-02).

In the Province of Saskatchewan there are two types of programme undertaken by the Provincial Government for assisting in the supply of drugs to patients. The first type consists of that Government's public health programmes under which the Government purchases drugs directly from the manufacturer, usually by competitive tender, through the Purchasing Agency. The drugs under these programmes are dispensed by the Public Health Department's agencies of which the principal ones are the Medical and Hospital Services Branch (Medical Services Division), Regional Health Services Branch (Communicable Diseases Division), and Psychiatric Services Branch (Institutions) (Hearing, pp. 760 and 775).

The other type of assistance is given to certain long-term beneficiaries of public assistance. The programme was established in 1945 to provide free drugs to recipients of Old Age Security Pensions and Blind Persons' Allowances who qualify for the provincial supplemental allowances and recipients of Mothers' Allowances as well as their spouses and dependents. Patients have their prescriptions filled through the ordinary retail channels. Prices of such prescriptions are

established on the basis of a maximum schedule of fees which has been agreed upon between the Department of Public Health and The Saskatchewan Pharmaceutical Association (Hearing, pp. 785-86). From December 1, 1948, a utilization charge of 20 per cent of the cost of approved drugs was paid by the patient. On April 1, 1959, this charge was increased to 50 per cent, so that half the cost of the prescription is borne by the province (Hearing, pp. 758-59).

Information about the supply of drugs to welfare recipients in the Province of British Columbia was given to the Commission by Mr. Douglas Denholm, Registrar, The Pharmaceutical Association of the Province of British Columbia. The price of prescriptions for which the cost is borne by the Government may not exceed the price determined according to a formula agreed upon between the Department of Social Welfare and the Pharmaceutical Association less 15 per cent. In no case may the price from which the 15 per cent deduction is made exceed the price ordinarily charged to the public (Hearing, pp. 1217-19).

CHAPTER XXII

COMPARATIVE PRICES OF DRUGS IN CANADA AND OTHER COUNTRIES

1. Comparisons of Retail Prices of Drugs in Canada and Various Foreign Countries

Chapter XVI of the Green Book presents information secured by the Director on prices of drugs in Canada in comparison with prices in other countries. Prices used for comparative purposes were obtained from information presented to the Kefauver Subcommittee (1) in the United States and from published compilations of Canadian and United States drug prices. The comparisons made from the latter sources are between prices of a product sold by a particular firm in the United States and the same product sold by a related firm in Canada.

Among the drugs for which comparative prices were given in the proceedings of the Kefauver Subcommittee were prednisone, chlorpromazine, prochlorperazine, meprobamate, Sparine and Serpasil. In the case of prednisone and sparine the only prices given were those to the retail druggist. In the case of the other drugs listed, both the price to the druggist and the price to the consumer were given.

Comparative prices to druggists of Merck's prednisone in bottles of 100 tablets are shown for ten countries in Table XXXIV of the Green Book (p.203). The prices range from \$7.53 in London, England, to \$27.78 in Tokyo, Japan. The price in Canada of \$20.80 (price listed in Canadian sources is given as \$19.87) is the fifth highest, standing next above the price in the United States of \$17.90.

Table XXXVA (Green Book, p.204) dealing with chlorpromazine indicates that the price to the druggist and the price to the consumer in Toronto are the highest of the prices in eleven countries. Because the prices to the druggist and to the consumer are available for each

(1)

Subcommittee on Antitrust and Monopoly, United States Senate.

of the countries listed except England, one can calculate the retail druggist's mark-up in each of these countries. (Mark-up is expressed as the percentage by which the price to the consumer exceeds the price to the retail druggist). On this basis the highest mark-up over the price to the druggist is taken in Dusseldorf, Germany, (95.9 per cent); second highest in Toronto (88.0 per cent); third highest in Sydney, Australia (79.8 per cent); fourth highest in United States (66.7 per cent). If the prescription fee incorporated into the Toronto price to the consumer is disregarded the mark-up becomes the same as that in the United States. It was pointed out to the Commission by Mr. S. N. Conder of the Canadian Pharmaceutical Manufacturers Association that the prescription price of \$7.05 for 50 tablets shown for Canada was derived from the list price of \$2.50 for 20 tablets (Hearing, pp.1864-68). There is also a list price of \$10.50 for 100 tablets (Green Book, p.187). If the druggist based his price on the latter the prescription price might fall between \$7.05 and \$6.00, or \$5.25 if the prescription fee is disregarded.

The comparative prices of the tranquillizing drug, prochlorperazine, Table XXXVB (Green Book, p.205) show that although the price to the druggist is the highest in the United States and second highest in Toronto, the price to the consumer is highest in Toronto and second highest in the United States. The highest mark-up over the price to the druggist is taken in Dusseldorf, Germany (97.5 per cent) and the second highest in Toronto (87.5 per cent). If the druggist's prescription fee were omitted from the Canadian price and the comparison made between the list price and the price to the druggist, the Canadian mark-up over cost (66.67 per cent) would be the same as the mark-up in the United States.

Table XXVI (Green Book, p.206) dealing with meprobamate shows that the highest prices charged the consumer for this drug occurred in Venezuela in which both brands, Miltown and Equanil, were sold for \$7.06 for 50 tablets of 400 mg. each. The price of Equanil to the consumer in Canada is shown as \$6.75 but a footnote to the table in the Green Book indicates that this includes a prescription fee of 75 cents. A higher price is shown for Miltown but the same footnote states that both drugs have the same list price in Canada. The brief of the Canadian Pharmaceutical Manufacturers Association points out that if the Canadian sales tax were excluded from the price of Equanil to the druggist, the price in Canada would be one cent lower than the price in the United States (Association brief, p.29; Hearing, p.1873). A comparison of the mark-ups over the price to the druggist indicates that the highest occur in Germany (92.75 to 104.41 per cent); second highest in Austria (93.59 and 96.67 per cent); and the third highest in Canada (87.5 per cent).

Comparative prices to druggists are shown for Sparine in nine countries with the Wyeth company as the supplier in eight (Green Book, Table XXXVII). The Canadian price is the highest and is slightly above that in the United States.

Table XXXVIII dealing with Serpasil indicates that the highest price to the druggist and to the consumer existed in the United States and that the price in Toronto was second. Again, the mark-up over the price to the druggist was highest in Dusseldorf, Germany (87.43 per cent); second in Vienna, Austria (80.94 per cent); and third highest in Toronto and in the United States (66.67 per cent in both cases).

Cyanamid of Canada presented the Commission with the following information on comparative prices of Achromycin in a number of countries:

"Lederle's Achromycin 250 mg. capsules in packages of 16 retail in both Canada (Federal Sales Tax included) and the United States at a suggested list price of \$7.11, and in packages of 100 at \$43.13. Prices to consumers in some foreign countries in U.S. dollars (as of September 1, 1961) are as follows:

<u>Achromycin</u>	<u>16's</u>	<u>100's</u>
Columbia	5.84	34.62
Greece	7.16	38.61
Costa Rica	6.01	34.80
Japan	6.00*	26.39
Mexico	5.59	33.73
Italy	5.81	-

* Adjusted from price for 100's "

(Cyanamid brief, p.16;
Hearing, pp.1480-81)

From the foregoing it appears that American and Canadian prices for packages of 100 are the highest for the eight countries for which information is presented. For packages of 16 the American and Canadian prices are exceeded only by that in Greece.

At a later stage of the proceedings counsel for Cyanamid

of Canada Limited informed the Commission that in Japan and Italy Achromycin is produced locally, but that in the other foreign countries listed above Achromycin is imported from the United States (Hearing, pp.3203-04).

It was submitted by certain witnesses that the proper way to compare prices of drugs in various countries was not in terms of the American dollar equivalent of the foreign price, but in terms of the number of hours of labour required in each country to earn the money required to purchase a given amount of a particular drug. This point of view was presented in the brief of Cyanamid of Canada:

"The staff of the Kefauver Subcommittee, at the hearings before that body, introduced several criteria to dramatize 'high' or 'excessive' prices paid by American consumers, one of those being that drugs can be purchased in foreign countries at much lower prices than in the United States.

In their statements and in colloquy with committee members and staff, industry witnesses explained that far lower costs of manufacture abroad coupled with far lower consumer-income account for lower dollar prices. Moreover, they produced evidence that the foreigner who may pay less in dollars from his lower income pays as much or more in hours of work to earn the price of his drugs. The same is true in Canada."

(Cyanamid brief, p.13-14; Hearing, pp.1470-71)

The point was elaborated in the following portion of the company's brief:

"On February 23rd, Dr. Austin Smith, President of the Pharmaceutical Manufacturers Association, introduced further evidence [before the Kefauver Subcommittee] that the U.S. dollar price tag is no valid measure of the true cost of drugs to the average man abroad. Taking the dollar equivalents of the price of a leading tranquilizer in six countries as introduced in Subcommittee Exhibit 98 on January 21 (Vol.7, page 1544), Dr. Smith presented the following table:

	<u>Retail Price in U.S. Dollars</u>	<u>Hours of work to buy 50 tablets</u>
France	.77	1 hr. 57 min.
U.S.A.	5.05	2 hrs. 18 min.
W. Germany	1.90	3 hrs. 18 min.
Italy	1.62	4 hrs. 46 min.
Japan	2.29	7 hrs. 38 min.

NOTE: Labour based on hourly earnings in manufacturing, U.N. Bulletin of Statistics; for Japan, Time Magazine, Dec.28, 1959.

The figure for the retail price in Canada in the above table has been quoted by the Director in his Statement at page 204, a figure of \$7.05. We calculate the hours of work required to buy 50 tablets in Canada would be somewhere in the region of 3 hours 49 minutes."

(Cyanamid brief, p.16; Hearing, pp.1479-80)

It does not appear to the Commission that calculations of the hours of work necessary to secure earnings equivalent to the price of a given amount of a particular drug are relevant to the question of the level of drug prices. Such calculations give no information of the relative costs of manufacturing and distributing drugs in the various countries and it is possible that in some instances the drug may be imported into several countries from the same source. The fact that different levels of wages prevail in different countries thus throws no light on the reasons why drug prices differ unless such differences in wages are related directly to the cost of the drugs in question.

2. Reasons Given to Account for Differences in Prices among Countries

Various reasons were given to the Commission in explanation of the differences in prices between Canada and the United States, on the one hand, and other countries. Mr. K. Antoft, of Nordic Biochemical pointed out that in many European countries the organization of the distribution of drugs differs greatly from that on the North American continent. He gave Denmark as an example where the number and location of pharmacies is rigidly controlled and the activity of the pharmacist is confined to pharmaceuticals. Mr. Antoft said that in Denmark there is one pharmacy for every 13,000 persons as compared with about 3,600 in Canada.

Prescription pricing is controlled by the government and pharmacists do much more preparation in their dispensaries than do druggists in Canada. In 1958, the average cost of prescriptions filled in Denmark was less than \$1.00 per prescription, whereas the average retail cost in Canada was \$2.78 (Hearing, pp.1397-1414).

The brief of Cyanamid of Canada quoted the following portions of the testimony of Mr. John T. Connor, President of Merck, before the Kefauver Subcommittee, with reference to the reasons for lower drug prices in some countries than in North America:

" . . . approximately 70 per cent of the steroid pharmaceutical sales abroad are of products produced wholly or in part by our foreign subsidiaries or branches . . . the consequence is that our costs are partially or wholly determined by economic conditions within the country of sale. We are all familiar with the fact that foreign material, labour and other costs of doing business are frequently far below our own. . .

It is evident that where we have the benefit of those lower costs, we can sell our finished pharmaceutical products at a lower price than would be possible in the United States.

. . . a pharmaceutical detail man in England is paid . . . about \$210 in U.S. money compared with \$600 or more a month in the United States."

(Cyanamid brief, p.14; Hearing, pp.1471-72)

Mr. Thompson of Cyanamid of Canada, in comparing costs in the United States and Canada with those of other foreign countries, said that in his company's experience taxes, depreciation, capital investment, wages of manufacturing employees and all marketing employees, employee benefits and distribution costs, are all lower in other countries, particularly in Europe and South America (Hearing, p.1483).

The brief of Cyanamid of Canada also cited testimony of Mr. Henry H. Hoyt, President, Carter Products Inc., before the Kefauver Subcommittee to the effect that in comparing foreign and American prices all factors involved must be taken into account, such as per capita income and real wages, and that prices of drugs in various countries should be related to the standard of living (Cyanamid brief, pp.14-15; Hearing, p.1472). As in the case of differences in the level of wages, the Commission does not consider that such factors are relevant to the question of differences in the prices of drugs, unless they can be related directly to their production or distribution.

Some discussions occurred between Mr. Thompson and members of the Commission as to the significance of wage rates in various countries determining costs of manufacturing and distribution (Hearing, pp.1473-75). The following extracts indicate the principal points brought out by Mr. Thompson:

"MR. WHITELEY: . . . At the same time comparison of relative wages may not be any more revealing.

MR. THOMPSON: Relative wages are an important ingredient in the cost of manufacturing and distributing drugs and with that question goes the freedom of the manufacturer in setting his prices. He has to live with wages in Canada if he is manufacturing and distributing in Canada, and he can live with a much lower wage scale if he is operating in Mexico, for instance.

MR. WHITELEY: It depends what his costs are in comparison to the wage rate. You may have low wage rates, but you may have an extremely low output, and the cost in output may be higher with your low wages than with high wages.

MR. THOMPSON: I understand.

. . .

MR. THOMPSON: . . . In the pharmaceutical industry, the equipment is basically the same. A tablet press is basically the same in Mexico as it would be in Canada, but the cost of the attendant who operates that press would be much lower in Mexico, and the productivity would not vary by a great deal, but the cost of the labour to create the production would be much lower and is much lower. Similarly, the cost of the detail man as was mentioned earlier."

(Hearing, pp.1474-75)

Mr. Thompson also testified that whether a product could be produced more cheaply in Europe or in the United States might be related to the extent to which automatically or semi-automatically controlled machinery was used. If a great deal of hand labour were involved the product would tend to cost less in Europe, but if the process of manufacture is largely mechanical there might be little difference in cost (Hearing, p.1728). In the latter case presumably the volume of output would be a major factor.

There was some evidence to the effect that the cost of raw materials was sometimes lower in foreign countries than in Canada.

Cyanamid of Canada imported sulphamethazine from Holland and bought other drugs from Europe as well (Hearing, p.1726).

Mr. J. R. Gilbert, President, Gilbert & Company, claimed that he could buy raw materials abroad, import them into Canada and re-export products at prices competitive on the world market (Hearing, p.2823).

3. Comparison of Prices to Consumers
in Canada and the United States

As previously mentioned, a comparison is made in the Green Book of the prices of certain drug products in Canada and the United States in the latter part of 1959. The products compared include ethical pharmaceuticals, proprietary drugs and vitamin preparations.

Ethical drugs for which prices are compared in the Green Book (Table XXXIX, pp.210-13) include penicillins, dihydrostreptomycin, broad spectrum and other antibiotics and tranquillizers. If each package size of drug is treated as a separate item (except in cases where a package of a particular size is listed for one country but not in the other) it may be said that there are 75 items contained in the table. Of this total, 11 were lower in Canada than in the United States. In the large majority of instances, therefore, the price was higher in Canada than in the United States. An error in Table XXXIX was drawn to the attention of the Commission by Schering with respect to the listing of prices for Trilafon. The prices shown for the United States are prices to the druggist whereas the Canadian prices are the suggested retail list prices. A comparison of Schering's prices of Trilafon to druggists in Canada and those in the United States is made below:

<u>Schering's Trilafon</u>			
	<u>Size</u>	<u>United States</u>	<u>Canada</u>
		\$	\$
<u>2 mg.</u>	50's	2.55	2.58
	500's	24.05	22.74
<u>8 mg.</u>	50's	4.25	5.01
	500's	40.25	42.42

(Canadian prices to retail druggists are from a letter to the Commission, dated May 2, 1961 from Schering Corp., Ltd., Montreal, P.Q.)

An examination of Table XXXIX of the Green Book reveals that the extent of the differences in prices between Canada and the United States varies for different products. The brief of Cyanamid of Canada contained the following comparison of prices of Cyanamid products by groups in Canada and the United States in July, 1960:

"SCHEDULE A

COMPARISON OF CYANAMID CANADA vs. U.S. DRUG PRICES

BASED ON PRICE TO RETAILER AS OF JULY, 1960

<u>Product Group</u>	<u>% Differential Canada vs. U.S.</u>
Antibiotics	+ 7.4
Hematinics	+10.5
Vitamins	+10.5
Biologicals	+18.9
Other Pharmaceuticals	+20.0
Total All Human Pharmaceutical Products	+11.2

. . . Canadian prices used for this comparison were published prices of the Medical Products Department, Cyanamid of Canada Limited, to the retail drug trade in Canada as of July, 1960. U. S. prices were those in effect at the same time for the same products offered in the United States to the retail drug trade by Lederle Laboratories Division, American Cyanamid Company. Canadian prices include the 11% Federal Sales Tax."

(Cyanamid brief, p.9; Hearing, p.1459)

It was explained that the comparison was made by taking the sales of the Canadian company in each product group and then calculating what the sales would have been at the prices of American Cyanamid in the United States (Hearing, p.1460). It was submitted that, exclusive of the Canadian sales tax, the prices of the antibiotic group of products of Cyanamid of Canada are lower in Canada than in the United States (Cyanamid brief, p.10).

Although comparisons of prices of prescription drugs indicate that generally prices are higher in Canada than in the United States the brief of The Canadian Pharmaceutical Association, Inc. drew attention to the fact that the average cost of a prescription in the United States has been somewhat above the Canadian average for a number of years. This would suggest that a larger proportion of more costly drugs is prescribed in the United States than in Canada. The comparison is set out in the Association brief as follows:

"23. There have been claims and this Commission has repeatedly heard statements which indicate that drug prices in Canada are higher than those in the U.S.A. In this context it is interesting to note that the average prescription price in the U.S.A., as determined in surveys conducted by The Lilly Digest, has been consistently higher than the Canadian average:

<u>Year</u>	<u>U.S.</u>	<u>Canadian</u>
1960	\$ 3.19	\$ 3.06
1959	3.09	2.98
1958	2.96	2.78
1957	2.85	2.61
1956	2.62	2.49
1955	2.46	2.26 "

(Association brief, p.111; Hearing, pp.2607-08)

The general relationship between prices in Canada and the United States which has been described in the case of antibiotics and tranquillizers is also seen in the case of proprietary drugs and vitamins listed in Table XL of the Green Book (pp.214-17). If each package size is treated as a separate item (except when the comparable size is not found in both countries), the total number of items in the table is 142. Of this number 5 were higher in price in the United States than in Canada, 10 were the same price in both countries and 127 were higher in Canada than in the United States.

A comparison of the prices of the products of 14 companies which are sold in Canada and the United States was included in the brief of the Canadian Pharmaceutical Manufacturers Association. The table, which is based on the differences between list prices in both countries, follows:

"DIFFERENCES BETWEEN DRUG COSTS
IN CANADA AND THE U.S.

Total Products Compared by each Company	No. higher in Canada	by %	No. higher in U.S.	by %
40	20	7%	8	10%
26	17	20%	5	10%
28	16	16.6%	12	4.4%
120	75	16.8%	42	18%
18	12	12%	3	11%
57	50	11.5%	7	15.2%
176	162	11.7%	14	32.3%
90	77	16.8%	13	21%
32	26	11%	6 (not incl.)	'Varies' (n inc)
213	0	0	1	40%
124	112	19%	10	17%
26	19	16.5%	5	22.5%
145	109	11%	12	15%
118	44	16.3%	74	32.6%
AVERAGES: 86	53	13%	16	19% "

(Association brief, p.27; Hearing, pp.1871-72)

The averages shown at the foot of the above table which are unweighted arithmetic averages do not appear to the Commission to provide a measure of the general differences in prices between the two countries for the products covered. It should be borne in mind that the Canadian list prices include the Federal Sales Tax of 11 per cent and that if the effect of this tax were excluded the differences in the case of Canadian prices which were higher would be reduced. The total number of products covered by the above table is 1213, of which 739 were higher in price in Canada than in the United States, and 212 were higher in price in the United States than in Canada. The remainder, 262, were presumably the same price in both countries.

4. Reasons Advanced for Differences in Price
between Canada and the United States

As has already been pointed out, the Federal Sales Tax was stressed by witnesses representing the pharmaceutical manufacturing industry and retail pharmacy as a significant factor increasing drug prices in Canada in comparison with the United States and other countries. In the case of products of Cyanamid of Canada, to which reference has already been made, it was pointed out that, apart from the increase caused by the sales tax, prices of antibiotics distributed by the company in Canada were lower than in the United States. For all products distributed by the company in Canada the difference in price level was about equal to the amount of the Federal Sales Tax (Hearing, pp.1463-64). It will also be noted that in the table set out in the preceding section of this report from the brief of the Canadian Pharmaceutical Manufacturers Association, there are several groups of products for which the differences in Canadian prices are not much more than the increase which would be caused by the sales tax, keeping in mind that the sales tax is imposed on the manufacturer's selling price.

Another comparison of the level of drug prices in Canada and the United States was also made in the brief of the Canadian Pharmaceutical Manufacturers Association by taking the products shown in Table XXXIX of the Green Book and removing the sales tax from the Canadian prices. On this basis the Association found that of the 69 items listed, prices (excluding sales tax) of 11 were the same or within 3 cents of each other, 30 were lower in Canada than in the United States and 28 were higher in Canada (Hearing, p.1876).

The following additional factors were given in the brief of the Canadian Pharmaceutical Manufacturers Association as reasons for the prices of drugs being higher in Canada than in the United States:

"1. Most raw materials must be imported from the U.S. and other nations, at a cost of anywhere from 15 to 20 per cent more than that paid by the U.S. manufacturer for the same materials. The same applies to manufacturing equipment.

2. The Canadian market is less than 10 per cent the size of the U.S. market, and therefore not conducive to comparable mass production techniques.

3. About 17 per cent of all pharmaceutical and medicinal products sold in Canada are imported, thereby cutting down still further on the size of the domestic market for Canadian manufacturers.

4. Because of the widely dispersed Canadian market, the Canadian manufacturer must pay more in transportation and

distribution costs than his U.S. counterpart."

(Association brief, p.30; Hearing, pp.1879-80)

The first factor listed would be relevant with respect to importations from the United States, but its effect with respect to importations from other countries would depend upon the terms on which such importations could be made compared with the costs of similar materials to a manufacturer in the United States. The brief of Cyanamid of Canada did not put stress upon higher raw material costs contributing to higher prices in Canada, but supported the view that marketing costs were higher in Canada because of the much smaller population, compared with the United States, the dispersed nature of the centres of population, and the fact that promotional material must be distributed in two languages. The much higher degree of mechanization which the large American market made economically justifiable was also endorsed as a factor leading to lower unit costs than in Canada. However, Mr. R. B. Thompson of Cyanamid of Canada admitted that not all costs were higher in Canada than in the United States. The fact that the Canadian company has been able to sell some products at prices no higher (apart from sales tax) than those in the United States suggests that there are some offsetting factors in connection with manufacturing in Canada (Hearing, pp.1464-69).

5. Differences in Prices of Drugs in Canada and Other Countries Reported by Consumers

The Commission received informally from several persons information about prices quoted for certain brand-named drugs in Canada as compared with prices of the same brand drugs in another country. As the informants had either purchased or received quotations for the drug in question and the information given was consequently a matter of direct knowledge and as the details given as to prices in Canada corresponded with or could be related to the suggested retail list prices of the manufacturer, it is considered that the other information furnished would be as reliable. It must be recognized that the information obtained in this way is of a random character and its representativeness has not been determined.

An Ottawa housewife informed the Commission in August 1962 that Tenuate Dospan (Merrell's brand name for diethylpropion) is distributed in Italy by Wm. S. Merrell, Inc., Milan, in packages of 10 tablets bearing a price to the public of 700 lire or about \$1.20 Canadian. The same drug could be purchased from an Ottawa druggist

at a price of \$6.75 for 30 tablets, which is Merrell's list price in Canada. The pro rata price for 10 tablets would be almost twice the price in Italy.

A resident of Edmonton, Alberta informed the Commission in October 1962 that on a visit to Great Britain she had inquired about the price of Librium and had been quoted a price equivalent to \$4.50 per 100 by a pharmacist in Edinburgh, Scotland and a price equivalent to \$4.00 per 100 in London, England. In Edmonton she had been quoted \$12.00 per 100 or \$6.00 for 50 at one drug store and \$10.00 per 100 or \$5.00 for 50 at another (Librium is Hoffman-La Roche's brand of chlordiazepoxide and is sold in 5 mg. and 10 mg. capsules). The list prices in the company's price list of January 1960 were \$9.00 per 100 for the 5 mg. capsule and \$12.00 per 100 for the 10 mg. capsule.

A resident of Vancouver, British Columbia wrote to the Commission in May 1961 that Lilly's Bilron could be purchased in Seattle, Washington at \$3.96 per 100 whereas in Vancouver the price was \$6.50 per 100. Retail prices in the United States as shown in the Drug Topics Red Book, 1960 were List Price \$4.40 per 100 and Fair Trade Price, \$3.96 per 100 for 5 gr. pulvules. The list price in Canada, according to the Price Book of Drug Store Merchandise, was \$6.00 per 100, to which a prescription fee might be added by the druggist.

A few instances of importations of drugs by consumers were reported to the Commission. A resident of Princeton, British Columbia informed the Commission in March, 1961 that he was importing Sandoz's Cafergot from a retail drug store in Mexico City at a laid down cost (including price of drug, air mail charges and customs duties and sales tax) of a little over \$9.00 per 100 whereas he was quoted \$5.55 in Princeton for 25 tablets.

The Sandoz catalogue lists Cafergot sugar-coated tablets each containing 1 mg. of ergotamine tartrate and 100 mg. of caffeine, at a suggested list price of \$16.18 per 100 and also Cafergot-PB, containing levorotatory belladonna alkaloids and sodium pentobarbital in addition to the drugs in Cafergot, at \$9.08 for 50. The druggist might add a fee for filling the prescription, including a charge for breaking the package.

A resident of Ottawa informed the Commission that he had imported Quinidine tablets 3 gr. from England where the price is equivalent to about \$2.15 for a bottle of 100 and about \$7.75 for a bottle of 500. The list price in Canada according to the Price Book of Drug Store Merchandise is \$25.00 per 500 for 3 gr. quinidine sulphate.

CHAPTER XXIII

THE USE OF PROPER OR BRAND NAMES IN PRESCRIBING DRUGS FOR PATIENTS OUTSIDE HOSPITALS AND ITS SIGNIFICANCE

1. Unavailability of a Proper Name for Many Pharmaceuticals Subject to Prescription Usage

The use of generic names⁽¹⁾ to designate drugs is restricted by the fact that for a large majority of them no such name exists or could be given. The Compendium of Pharmaceutical Specialties, published in 1960 by The Canadian Pharmaceutical Association, Inc. under the editorship of Dean F.N. Hughes of the Faculty of Pharmacy of the University of Toronto, provides a source of information embracing as far as possible all brand-named ethical drugs enjoying a wide distribution in Canada. It also lists a few drugs under their official or non-proprietary or chemical names, e.g., thiamine chloride, penicillin, reserpine, sulphonamides, etc. The 7776 products described in the Compendium have been classified by Professor J.G. Nairn of the University of Toronto in an analysis contained in Appendix G to the brief presented to the Commission by The Canadian Pharmaceutical Association, Inc.

As shown in Table 30, it appears from the analysis that 37.72 per cent of the listed drugs could be prescribed either by generic or by brand name designations. However, this choice open to physicians is of practical significance only with respect to 29.41 per cent of the listed products, because the difference - 8.31 per cent - could be obtained from one company only. As pointed out in the brief of The Canadian Pharmaceutical Association, Inc.:

"It would be erroneous to conclude that approximately one-third of all prescriptions could be written generically, as no figures related to potential utilization of the drugs so classified are known. Further there is no way of determining the extent to which the availability of other specialty formulations and/or mixtures is made possible through the sale of the single ingredient product by any one manufacturer. . . ."

(Association brief, p. 43;
Hearing, p. 2407)

(1) As indicated in section 2 of Chapter II, the terms "generic", "proper" and "non-proprietary", as applied to the names of drugs, have the same meaning.

Table 30

Classification of the 7776 Drugs Described
in the Compendium of Pharmaceuti-
cal Specialties, 1960

<u>Class</u>	<u>Number</u>	<u>Percentage of total number</u>
Products used only in hospitals	85	1.09
Products available on the Canadian market through normal sources	7691	98.96
1 - Mixtures of drugs, that-is-to-say products containing 2 or more active ingredients (exceptionally extracts from a single plant are considered as single drugs, even if they contain more than one active ingredient)	4593	59.07
2 - Single drugs	3098	39.89
(a) Having a generic name and prepared by more than one company	2287	29.41
(b) Having a generic name and prepared by one company only	646	8.31
(c) To which no generic name has yet been assigned	165	2.17
Total	7776	100.05
	7691	98.96
	3098	39.89

Sources: Appendix G to the brief of The Canadian Pharmaceutical Association, Inc.; letter dated May 8, 1962 from Mr. J.C. Turnbull, Secretary-Manager of the C.Ph.A.; letter dated June 27, 1962 from Professor J.G. Nairn, of the University of Toronto.

2. Percentage of Drugs of which at Least One
Preparation is Marketed under its
Proper Name Only

While the so-called generic manufacturers specialize in marketing products under their proper names only, many brand name companies also sell products which carry no proprietary name. According to the brief of the Canadian Pharmaceutical Manufacturers Association:

" . . . A survey of 39 companies which we undertook in August past [1961] showed that 18 of these firms sell more than 400 products under generic name alone. And these companies are considered prestige firms by the medical profession. . . ."

(Association brief, pp. 49-50;
Hearing, p. 1911)

Some of the factors which determine the drugs for which there are generic preparations are indicated in the evidence of the following witnesses:

(a) Mr. Douglas Denholm, Registrar of The Pharmaceutical Association of the Province of British Columbia:

"Our information certainly indicates that manufacturers who distribute their products by the generic name only limit a lot of their products to products which are in volume demand. . . ."

(Hearing, p. 1297)

"Size has nothing to do with it. Some large ones do, some small ones do. Some of the biggest manufacturers sell phenobarbital, this is the generic name, sir, without any brand name at all."

(Hearing, p. 1301)

(b) Mr. K. Antoft, President of Nordic Biochemicals Limited:

"MR. MacLEOD: What factors do you take into consideration when determining whether you will sell under the trade name or under the generic name?"

MR. ANTOFT: Our Duracton, which has been mentioned, this is corticotropin with carboxymethylcellulose,

and it is obvious there why should we use a trade name. . . .

. . .

MR. MacLEOD: The point is that the illustration that you have given, you use a trade name because it is simpler than a generic or chemical name?

MR. ANTOST: That is right.

MR. MacLEOD: Are there any other reasons which would influence you?

MR. ANTOST: Well, of course also the name Duracton, because it is a unique substance. It has certain characteristics that are not shared by other forms of ACTH, which makes it readily identifiable by a physician as being a substance that has certain activities that he associates with the name.

MR. MacLEOD: In this instance there would be no question of going and buying the same product under its generic name, because it would not be on the market?

MR. ANTOST: Yes, it just does not exist. This is a case, I think I can say very safely that this is the case with all our products that are sold under trade names, that is that there is no corresponding generic name for these particular products.

MR. MacLEOD: Let us go to the reverse case, the products which you sell under generic names. What would influence you to adopt that policy?

MR. ANTOST: For example, we sell potassium chloride tablets, which are a very simple and uncomplicated type of medication. It would be presumptuous to give this a trade name, and try to pass it off as other than potassium chloride.

MR. MacLEOD: In your case, do your products fall into two extremes, on the one hand unique, and on the other hand common?

MR. ANTOST: No, not necessarily. I think there are many graduations in between. We for example sell a straight ACTH, without any admixture, which we sell under a trade name, Corticotropin-Nordic, which indicates the manufacturer.

MR. MacLEOD: Are there other brands of ACTH on the market that are sold under trade names?

MR. ANTOFT: Yes, there are several others.

MR. MacLEOD: So that a doctor prescribing ACTH has the choice of prescribing that drug under the brand name of other manufacturers, or under generic name, in which case your product at least will be available?

MR. ANTOFT: Yes, that is correct. He would, if he prescribed corticotropin, he would be getting a short-acting preparation which is useful, but whose usefulness is somewhat limited. If he prescribes any of the long-acting types of preparations, then he is trying to define the type of activity which he expects from this particular drug which he is prescribing."

(Hearing, pp. 1431-34)

In his evidence to the Commission, Mr. Denholm estimated at five per cent the percentage of drugs of which at least one generic preparation is available on the Canadian market (Hearing, p. 1298). However, as he did not take into consideration the varying degree of utilization of the various drugs and if, as he contended, preparations marketed under their proper names only are usually in volume demand, it follows that substantially more than five per cent of all prescriptions might be filled with generic preparations, if doctors were prescribing by proper name whenever it could be done.

3. Share of all Prescriptions which is Actually Written with Proper Names

The Commission received information about the results of six surveys giving indications as to the percentage of all prescriptions which is actually written with proper names.

According to the Report of the Joint Committee on the Retail Structure of Drug Prices in Manitoba, ⁽¹⁾

(1) Report of the Joint Committee on the Retail Structure of Drug Prices in Manitoba. A study carried out by a Joint Committee of The Manitoba Pharmaceutical Association and the Government of Manitoba, Winnipeg, Manitoba, May 1961, p. 68.

" . . . A recent study by the Pharmaceutical Association of a representative group of 500 prescriptions dispensed in Winnipeg revealed that approximately 8 per cent were prescribed by generic name. . . ."

The survey referred to above was carried out in the Fall of 1960 by obtaining the most recent 50 prescriptions from 10 pharmacies selected at random⁽¹⁾.

In the Province of Alberta, 3,491 prescriptions were analysed by The Alberta Pharmaceutical Association. The survey was conducted by checking the records of 40 drug stores in the following cities and towns: 15 in Edmonton, 14 in Calgary, 4 in Lethbridge, 2 in Barrhead, 2 in Claresholm, 2 in Red Deer and 1 in Mannville. These stores were selected as representative of the various types of pharmacies operating in the province. The sample included downtown, shopping centre and suburban pharmacies. It also included one-man stores as well as stores with a number of pharmacists and clerks. The method followed was to check in the majority of cases every one-hundredth and in some cases only every two-hundred and fiftieth prescription written over a period of three years. As shown in Table 31, the results of the survey establish, among other things, that 243 prescriptions or 6.69 per cent of total were written using generic terminology.

In May, 1961, the Canadian Pharmaceutical Journal⁽²⁾ published the results of a survey conducted by Dean F.N. Hughes and Professor G.C. Walker. The sample consisted of 902 prescriptions supplied by Prescription Services Incorporated of Windsor, Ontario. Six hundred and sixty-five of them had been consecutively written during February, March and April of 1960 and the remainder, 237, in June of the same year. However, as 13 could not be analysed, the total number may be considered to be 889. As shown in Table 32, 63 or 7 per cent were written with generic names. This indeed is pretty close to the percentage of 6.69 per cent revealed by the survey conducted in Alberta.

(1) This information was conveyed to the Commission in a letter dated July 31st, 1962 by Mr. J. Frank Holland, who at the time of the hearing held in Winnipeg was President of The Manitoba Pharmaceutical Association.

(2) Walker and Hughes, "A Prescription Drug Survey", Canadian Pharmaceutical Journal, Vol. 94, No. 5, May 1961, pp. 22, 23 and 38.

However it must be pointed out that generic terminology may also have been used in some or all of the extemporaneously compounded prescriptions representing 3.97 per cent of total in the Alberta and 5 per cent in the Ontario survey. Consequently the percentage of prescriptions written with proper names is somewhere between 6.69 and 10.66 per cent in the first case and 7 and 12 per cent in the other. Indeed it is much closer to the lower limits if in writing prescriptions for extemporaneously compounded pharmaceuticals doctors show the same preference for brand name terminology as in prescribing drugs compounded at the manufacturer's level. It should be noted however that one physician, Dr. J.W. Reid, practising in the City of Halifax, told the Commission that he was resorting to generic terminology, when prescribing combinations of his own:

"MR. MacLEOD: In your practice do you ever prescribe drugs under their generic names?

DR. REID: Well, yes I do. I do when I am prescribing. I still attempt to prescribe pharmacopaedic drugs that have been in use a long time and are standard preparations which are not expensive. Where I think they are adequate, I will use those drugs prescribing from a generic name. I would do that with some of the newer drugs, too, but perhaps not too frequently actually. I would mostly prescribe from the brand names, I think.

MR. MacLEOD: There are certain drugs which may only be sold legally under a doctor's prescription, is that correct?

DR. REID: That is correct.

MR. MacLEOD: Does a doctor in his practice find it necessary to write prescriptions for other drugs for which no prescription is legally required?

DR. REID: Yes.

MR. MacLEOD: Would it be in respect of those drugs that you might use generic names? We are speaking of older, more established drugs.

DR. REID: Yes, that is correct, but also some of the newer preparations such as meprobamate. For instance, I prescribe meprobamate rather than the brand name, not being too much aware personally of just what difference in cost there might be. Prescribing in that particular way, if I did prescribe from a generic name it would be because I was making my own combination with some other drugs to be dispensed as a mixture.

MR. MacLEOD: Something that the druggist would have to put up in his own shop?

DR. REID: Exactly. I make a point wherever I can of prescribing in that way to make work for the druggists. I don't want them to lose all their skills.

. . .

THE CHAIRMAN: Our information is in modern practice there are a great many prepared dosages and in a great many instances the doctor prescribes a drug that is already fully prepared. It is prescribed and the druggist simply marks a bottle or package.

DR. REID: That is true. We have to do that with many of the new chemicals because they come just in that way and there is no other way to prescribe them. We can, of course, eventually if we find a new drug might work better with something else we can make our own dosage form and have the druggist make it up, which we do.

We would generally specify that drug by its generic name and add what we wish to it and the druggist would then make it up accordingly."

(Hearing, pp. 392-98)

Table 31

Breakdown of 3,491 Prescriptions Written in
7 Cities Located in Alberta

	<u>Number</u>	<u>Percentage</u>	<u>Average Price per Prescription</u>	
			\$	
Extemporaneously compounded prescriptions ⁽¹⁾	129	3.97		
Prescriptions compounded at the manufacturer's level	3362	96.03		
Non-Proprietary prescriptions, that-is-to-say prescriptions using non-proprietary names ⁽²⁾	243	6.69	1.67	
Brand name prescriptions, that-is-to-say prescriptions written for brand name products	<u>3119</u>	<u>89.34</u>		
Total	3491	3362	100.00	96.03
				3.15

- (1) There is no indication as to whether these prescriptions were written using generic or brand name terminology.
- (2) Doctors using non-proprietary terminology in prescribing often require that the prescription be filled with the product of a specified generic drug manufacturer. This has the effect of preventing the pharmacist from filling the prescription with a brand-named product.

Source: Brief of The Alberta Pharmaceutical Association, supplemented by a letter dated October 12, 1961 from Mr. Donald Cameron, Registrar-Treasurer of the Association.

Table 32

Breakdown of 889 Prescriptions Filled in 1960
in the Windsor Area

	<u>Number</u>				<u>Percentage of Total Number</u>			
Extemporaneously compounded prescriptions ⁽¹⁾	45				5			
Prescriptions compounded at the manufacturer's level:	844				95			
Non-proprietary prescriptions that-is-to-say prescriptions using non-proprietary names ⁽²⁾	63				7			
Brand name prescriptions, that-is-to-say prescriptions written for brand name products:	781				88			
1. Mixtures (2 or more medicinal ingredients)	376				42			
2. Single drugs for which	405				46			
(a) there is no other available ⁽³⁾ preparation	121				14			
(b) all other available preparations are marketed under brand names	35				4			
(c) at least one other available preparation is marketed under a generic name	249				28			
Total	889	844	781	405	100.	95.	88.	46.

- (1) There is no indication as to whether these prescriptions were written using generic or brand name terminology.
- (2) Each of these prescriptions was for a drug for which there was at least one generic preparation.
- (3) The availability of the product is considered with respect to the Canadian market as a whole.

Source: Walker and Hughes, "A Prescription Drug Survey", Canadian Pharmaceutical Journal, Vol. 94, No. 5, May 1961, pp. 22, 23 and 38; Letter dated May 3rd, 1962 addressed to the Commission by Dean F.N. Hughes; Letter dated May 8th, 1962 addressed to the Commission by Professor G.C. Walker.

Table 33

Breakdown of 500 Prescriptions Filled at Mr.
J. Frank Holland's Pharmacy, Winnipeg,
in each of the years 1960 and 1962

	<u>1960</u>		<u>1962</u>	
	<u>Number</u>	Percentage of Total <u>Number</u>	<u>Number</u>	Percentage of Total <u>Number</u>
Non-proprietary prescriptions:	62	12.4	71	14.2
Brand name prescrip- tions with generic equivalent	186 ⁽¹⁾	37.2	239	47.8
Brand name prescrip- tions with no generic equivalent	252 ⁽¹⁾	50.4	190	38.0
Total	500	100.0	500	100.0

-
- (1) The availability of generic drugs for the 1960 sampling was established by the use of various 1960 catalogues from several different companies specializing in such products.

Source: Letter dated July 31st, 1962 and addressed to the Commission by J. Frank Holland, immediate past President of The Manitoba Pharmaceutical Association.

Mr. J. Frank Holland, immediate past President of The Manitoba Pharmaceutical Association, made two surveys similar to that conducted by Dean F.N. Hughes and Professor G.C. Walker: one for the year 1960 and the other for the year 1962. Each covered 500 prescriptions taken from the files of his own pharmacy and consecutively written during the early months of the year. As shown in Table 33, these surveys establish, among other things, that 62 prescriptions in 1960 and 71 in 1962 were written using generic terminology. These figures represent respectively 12.4 per cent and 14.2 per cent of the total. A possible explanation for this slight increase from 1960 to 1962 is that doctors may be more conscious about the cost of medication because of the publicity recently given to the subject. This increased concern on their part has been pointed out as follows by two practising doctors:

(a) by Dr. Nathan Schechter, Chairman of the Pharmacy Committee of the Ottawa Civic Hospital;

"MR. MacLEOD: I do not want to put you on the spot, Doctor. Are you yourself fairly familiar with the prices that the patients will have to pay for drugs that are prescribed, or is it possible for you to keep up with that information?

DR. SCHECTER: Well, actually I think perhaps I have interested myself in the costs of drugs to patients during the last couple of years, with also checking prices of the same drugs, the generic and the brand names, and there, of course, is a big discrepancy between the two.

MR. MacLEOD: The brand name is higher.

DR. SCHECTER: The brand name is always higher.

MR. MacLEOD: That covers the personal situation, as you have explained, with a special interest in this field. Is it your opinion that doctors generally and doctors in general practice would know the prices of the drugs which they prescribe; the cost of prescribing different drugs.

DR. SCHECTER: Probably not, unless they were directly connected in some way with it; although I think since the publicity about it more and more of the doctors have familiarized themselves with the costs.

It is difficult to know the cost of all the drugs but I think that we are much more familiar with it now, as a result of the publicity, than we used to be."

(b) by Dr. F.B. Rodman, Assistant Clinical Professor of Therapeutics at the University of Alberta:

"MR. MacLEOD: Are you able to express any opinion on whether doctors generally know the cost of drugs they prescribe?

DR. RODMAN: Yes, I think I can. I think six months or a year ago they were horribly deficient in this field. I think that attitude is changing very rapidly and they are becoming very conscious of the cost. Certainly among the interns they are exceedingly conscious of the cost."

(Hearing, p. 908)

If the above hypothesis is accepted for the slight increase in the proportion of non-proprietary prescriptions from 1960 to 1962 and if like Dr. J.W. Reid all physicians had been using generic terminology when prescribing combinations of their own, then the results of the respective surveys conducted by Mr. Holland on the one hand and Dean Hughes and Professor Walker on the other are perfectly reconciled. However they show somewhat higher percentages than those established by the surveys conducted in Manitoba by the Joint Committee, and in Alberta. An explanation for the existing discrepancies may well be the proximity of Mr. Holland's drug store and of Prescription Services Incorporated to certain types of medical practitioners. Indeed, in a letter dated July 31, 1962, Mr. Holland conveyed the following information to the Commission:

"... it is interesting to note that my own study shows more prescriptions prescribed by generic name than either of the others [the one conducted by The Manitoba Pharmaceutical Association and the other made by Dean Hughes and Professor Walker], which I believe to be due to the fact that we have, within 100 yards of our pharmacy, three general practitioners who are constantly ordering the simpler drugs and preparations (APC, digitalis, phenobarb, sodium salicylate, etc.)."

It should be pointed out that distortion is less likely to appear in the results of the surveys conducted in Manitoba by the Joint Committee and in Alberta where the prescriptions analysed were taken from the files of a representative group of pharmacies.

A more recent survey than any of the five described above was conducted by Drug Merchandising, and was based upon the largest sample of them all, as a questionnaire was mailed to 1000 pharmacists. Usable replies totalled 262 giving a 26.2 per cent return. According to this survey, only 5.6 per cent of prescriptions were written with proper

This percentage is the lowest of all. At first sight, this result throws some doubt on the hypothesis according to which the proportion of prescriptions actually filled with generic preparations has increased in recent years. However, the discrepancy between this percentage and those established by the earlier surveys may well be due to differences in sampling methods, for the survey conducted by Drug Merchandising also yielded the following results:

"While generically-written prescriptions are only a small part of total prescriptions, they show a definite, but small increase. During the past year generic prescriptions have increased according to 44% of the druggists. Nearly 7% of druggists said generic prescriptions are decreasing, while 44.6% said they have stayed the same."(1)

At all events, if we take the information received from all sources, 5.6 to 14.2 per cent of all prescriptions were written in generic terms.

4. Percentage of Prescriptions which is Actually Filled with a Generic Product

The Commission did not receive any precise information with respect to the share of all prescriptions which is actually filled with a generic product, that is to say, with a drug marketed under its proper name only. However, at the time of five of the six surveys referred to in the preceding section, it could not exceed the share of non-proprietary prescriptions, because it was then illegal for a pharmacist in any Canadian province to substitute another preparation of a drug for that specified by a doctor in a brand name prescription. This aspect of the legislation was commented on as follows before the Commission by Dr. C.A. Morrell, Director of the Food and Drug Directorate:

"MR. FRAWLEY: Dr. Morrell, dealing with the matter of generic names as against brand names, if there is any merit in getting away from brand names and going to generic names can anything be done unless the physician who writes this prescription does it?

DR. MORRELL: You mean it is up to the physician to decide whether he is going to write generic or brand names?

(1) "Most Generic Prescriptions Filled With Brand Name Products", Drug Merchandising, Vol. 43, No. 7, July 1962, p. 24.

MR. FRAWLEY: Might I put it this way, if a physician gives me a prescription and uses a brand name - I don't know how I would, but suppose I could find out, perhaps I could look at Mr. MacLeod's green book and get the generic name and I walked into the drug store and said here is a prescription and I want so and so, using the generic names. Would he tell me to be on my way?

DR. MORRELL: I think ethically he would have to tell you that.

MR. FRAWLEY: He would have to fill it?

DR. MORRELL: He would have to fill the prescription as written.

MR. FRAWLEY: He would tell me to take my prescription back to the doctor if I wanted generic names.

DR. MORRELL: Yes, that is probably true."

(Hearing, pp. 146-47)

Indeed the percentage of prescriptions which was actually filled with a generic product was smaller than the share of non-proprietary prescriptions to the extent that the latter might have been filled with brand-named preparations. Such a course of action was inevitable in cases where there was no generic name preparation available on the Canadian market to fill a non-proprietary prescription⁽¹⁾ Where a generic equivalent was available, filling non-proprietary prescriptions with brand-named preparations was and still is permitted in the absence of any indication in the written prescription that the product of a particular generic manufacturer should be dispensed by the pharmacist. For instance, in the absence of any such indication, Equanil, which is Wyeth's brand of meprobamate, may well be dispensed by a pharmacist to a client for whom meprobamate has been prescribed, even if a generic preparation is available on the Canadian market. In this respect, the Drug Merchandising survey gave the following information:

"... 62% of the druggists fill a generic prescription with a brand name product and 30% fill it with a generic product."⁽²⁾

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- (1) This possibility did not materialize in the survey conducted by Dean Hughes and Professor Walker.
- (2) "Most Generic Prescriptions Filled with Brand Name Products", Drug Merchandising, Vol. 43, No. 7, July 1962, p. 24.

The above considerations do not apply any longer in their entirety to Alberta where the proportion of prescriptions which is actually filled with generic preparations may theoretically exceed the proportion of non-proprietary prescriptions since the amendment⁽¹⁾ made in April 1962 to The Alberta Pharmaceutical Association Act, adding section 45 thereto, which section reads as follows:

"45. Where a prescription refers to a drug or drug combination by a brand name or a name other than its generic name, a pharmaceutical chemist, in dispensing the prescription, may use a drug or drug combination that is the generic or brand name equivalent of that named in the prescription unless the prescriber indicates otherwise

- (a) by designating the name of the manufacturer,
or
- (b) by specifying that no equivalent is to be dispensed."

This enactment is clearly intended to promote the sale of generic preparations. It is obvious, however, that its effectiveness will depend upon the behaviour of doctors and pharmacists. It will be totally ineffective if all brand name prescriptions are written by doctors on pads on which are already printed the words: "no substitution" or filled by pharmacists with brand-named preparations, even in cases where a substitution is possible. This last possibility may well materialize if pharmacists avoid making any substitution whatever under this enabling legislation because of fear of increasing thereby their legal responsibility.

5. Proportion of all Prescriptions which can be Written with Proper Names

According to the study made by Dean F.N. Hughes and Professor G.C. Walker, 405 prescriptions were written for brand-named single drugs. As we know, most single drugs have a non-proprietary name. Indeed the analysis made by Professor J.G. Nairn shows that approximately 19/20 of the single drugs listed in the Compendium of Pharmaceutical Specialties do have a proper name. By applying this percentage to the figure of 405⁽²⁾, it is possible to

(1) Statutes of Alberta, 1962, c. 61, s. 3.

(2) Of course this method does not take into consideration the degree of potential utilization of the various drugs.

conclude that generic terminology might have been used in approximately 385 prescriptions actually written for brand-named pharmaceuticals. As 63 prescriptions had been actually written with proper names and 45 others had been extemporaneously compounded, altogether 448 to 493 prescriptions representing 50 to 55 per cent of grand total of 889 could have been written with non-proprietary terminology.

As an estimated 115⁽¹⁾ of these 448 prescriptions were for drugs for which only one preparation was available, in each case a brand-named preparation, the decision taken by doctors as to whether they should use generic or brand terminology was of some practical significance with respect to 333 prescriptions representing 37 per cent of grand total. In contrast to this percentage only 7 to 12 per cent had been actually written with non-proprietary terminology. However the results of the surveys made by Mr. Holland give still more practical significance to the choice open to the physicians. As shown in Table 33, the single group of brand name prescriptions with generic equivalents accounted for not less than 37.2 per cent of total in 1960 and 47.8 per cent in 1962. Moreover it is likely that for either year some brand name prescriptions with no generic equivalent and many non-proprietary prescriptions were for drugs for which there was more than one preparation. Particularly revealing is the discrepancy between the percentages for 1960 and 1962 of brand name prescriptions with no generic equivalent. It may result from an increase in the availability of generic preparations and/or from the greater difficulty of ascertaining retrospectively the existence of a proprietary equivalent.

6. Estimated Share of Total Prescriptions which
may be Filled with Products Marketed
under their Proper Names

Some of the surveys referred to above give an indication with respect to the percentage of all prescriptions which might have been filled by products marketed under their generic name, had not the doctors restricted the initiative of the pharmacists by prescribing brand-named products in a number of cases where generic preparations were available in the Canadian market.

Of the 405 prescriptions for brand-named single drugs analysed by Dean F.N. Hughes and Professor G.C. Walker, 249 were for a drug for which at least one preparation was marketed in Canada under a proper name⁽²⁾. This is also true with respect to the 63 non-proprietary prescriptions. By adding these two figures we get a total

(1) 115 is to 385 what 121 is to 405.

(2) Indeed the figure may be slightly higher than 249. For the authors of the survey may have missed a few cases because of the difficulty of ascertaining that no firm is actually marketing a particular drug in Canada under its proper name.

of 312 prescriptions which could actually have been filled by generics, that is to say, by drugs marketed under a non-proprietary name. This represents 35 per cent of the grand total of 889 prescriptions. As a contrast to this percentage, 12 per cent at a maximum and in all likelihood substantially less than this was actually filled with generics.

In this respect also the study made by Mr. Holland gives another picture of the facts. As already pointed out, the single group of brand name prescriptions with generic equivalent represented 37.2 of the total in 1960 and 47.8 per cent in 1962. Moreover the existence of a generic preparation may be presumed for many, if not all, prescriptions of the non-proprietary group⁽¹⁾. For this reason prescriptions which could have been filled by generics may have accounted for 37.2 to 49.6 per cent of the total in 1960 and 47.8 to 62 per cent in 1962. As a contrast, respectively 12.4 and 14.2 per cent at a maximum and in all likelihood substantially less were actually filled with generic preparations.

The studies made by Dean Hughes and Professor Walker on the one hand and by Mr. Holland on the other show widely divergent results. However their variance is not due only to the small samplings. To some extent it may reflect the varying degree of success met by the authors in overcoming the difficulty of ascertaining the existence of a generic preparation. It may also be accounted for by regional or locational factors and, more especially, by seasonal variations. In this respect, the following information was conveyed to the Commission by Mr. Holland:

"While checking our files I also noted that, in many cases, the season affects statistics considerably as during the period from September to March we dispensed more antibiotics (highly competitive with many generic equivalents) than during the summer months, and correspondingly during the summer dispensed more compounded lotions, ointments, and external preparations which of course would have no generic equivalents."⁽²⁾

In this connection, it should be recalled that all prescriptions examined by Mr. Holland were for the early months in each of the years 1960 and 1962, while 237 of the 889 prescriptions analysed by Dean Hughes and Professor Walker were for June 1960.

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- (1) Actually there was one generic preparation for each of the 63 non-proprietary prescriptions analysed by Dean F. Hughes and Professor Walker.
 - (2) Letter dated July 31st, 1962 and addressed to the Commission by Mr. J. Frank Holland, immediate past President of The Manitoba Pharmaceutical Association.

In each case however the availability of a generic preparation was considered with respect to the Canadian market as a whole. For this reason, prescriptions which could have been filled with generics without inconvenience to the pharmacist or the patient represent a smaller percentage than indicated above. According to the results of the survey made by The Manitoba Pharmaceutical Association, this percentage was 18 to 20. As noted previously, approximately 8 per cent of a total of 500 prescriptions had been written with generic names. However:

"... an additional 10 to 12 per cent were of sufficiently simple chemical formulae that they could have been prescribed and dispensed by generic name."⁽¹⁾

As to the meaning to be attached to the word "dispensed" in the above quotation, some precision was afforded by Mr. Holland, who at the time of the hearing held at Winnipeg was President of The Manitoba Pharmaceutical Association:

"... from our experience, while the existence of an equivalent generic product may be a fact, often it is next to impossible to obtain it from local wholesalers or depots. This factor alone would tend to exclude this type of prescriptions from the 10-12% which could have been prescribed and dispensed by generic name."⁽²⁾

If the information from all sources is taken, the percentage of prescriptions for drugs for which a generic preparation was available on the Canadian market varied from 35 to 49.6 in 1960 and may have been as high as 62% in 1962. However the percentage of prescriptions for drugs with respect to which a generic preparation could conveniently be dispensed may have been as low as 18 to 20 per cent.

(1) Report of the Joint Committee on the Retail Structure of Drug Prices in Manitoba, p. 68.

(2) Letter dated July 31st, 1962 and addressed to the Commission by Mr. J. Frank Holland, immediate past President of The Manitoba Pharmaceutical Association.

7. Behaviour of Doctors with Respect to
Prescribing by Proper or Brand
Names

The survey conducted by Professors Walker and Hughes throws some light on the general attitude of doctors with respect to prescribing by proper or brand names. From its results, it appears that, of 889 prescriptions, 468 could have been written with proper names. As only 121 of these 468 were for drugs for which only one preparation was available, prescribing by proper or brand names had some practical significance with respect to not less than 347 prescriptions. If we take this figure as a total, only 63, or 18 per cent approximately, were written with proper names. With respect to the other 284, the use of brand names prevented the pharmacist from dispensing any other preparation than that specified by the physician. It is also significant that 249 of these last 284 prescriptions were for drugs for which there was at least one preparation marketed in Canada under a proper name. This represents approximately 72 per cent of the total of 347 prescriptions.

The reasons why physicians show a preference for brand name terminology when prescribing for private patients outside of hospitals appear clearly in the following excerpts from the evidence given before the Commission by six medical witnesses:

(a) by Dr. Nathan Schechter, medical practitioner in the City of Ottawa and Chairman of the Pharmacy Committee of the Ottawa Civic Hospital:

"MR. MacLEOD: In your opinion would it be desirable for doctors to use the generic names generally in prescribing?

DR. SCHECTER: Yes, I think that it would be desirable for the reasons that I mentioned, except that we are somewhat concerned about the quality of a drug that would be dispensed in certain cases with the generic name.

There are generic name companies and we have not as yet had a definite indication from the Food and Drug Department that they are all quality wise in the ethical field. There is some fear on the part of the physician that the quality of the drug may not be up to par and so we hesitate using generic names too widely as yet.

I think that when and if the Food and Drug Department say they are all right, have the proper quality controls and so on, we will have no hesitation in ordering generic name drugs.

. . .

MR. MacLEOD: As a matter of interest do you prescribe outside of the hospital for private patients?

DR. SCHECTER: Yes.

MR. MacLEOD: What names do you use there?

DR. SCHECTER: I use the generic names fairly frequently but as I say in cases where I am not sure about the quality I use the brand name product. I am not saying that generic name companies are not good but we are still somewhat hesitant about ordering by generic names exclusively."

(Hearing, pp. 260-62)

(b) by Dr. Charles Henry Reardon, medical practitioner in the City of Halifax and member of the Legislative Assembly:

"MR. MacLEOD: Yes, I am getting your reaction as a doctor in general practice?

DR. REARDON: I would say that primarily I prescribe trade names because they are easier to remember and it is the way that you are used to doing it and you get into a habit of doing it.

MR. MacLEOD: That is your practice?

DR. REARDON: If I prescribe by the generic name I would feel obliged to add to that one of the companies who supplied that drug who I felt supplied quality drugs.

I don't think all the drugs coming into Canada are quality drugs and I feel that we have an obligation to our patients to see to the best of our ability that what they get is the best. The prime consideration in drugs, to my point of view, is to see that the drug will do the job that you want it to do. Price is not the prime consideration. The prime consideration is getting the patient better. After that the price must come into it, but the prime consideration is to see that the patient gets the drug that will cure that patient for that particular disease.

. . .

All the drugs are not examined by the food and drug group in Ottawa as for quality, biological and chemical quality or quantitative properties. There is no good using a drug because it is cheap if you are going to get hills and valleys in its potency in the action that it will have. If you are going to get hills and valleys, you do not know why your patient is not responding to that drug, and it is like anything else.

Over the years you get to recognize that a company, whether it is A, B, or C, has put out drugs that certainly as far as you know, and you have never heard of it being otherwise, that have in their capsules or in their tablets or the kind of medicine involved, what that company say is there.

It is like having a Rolls-Royce. You don't worry about the quality because over the years you come to recognize that it is there and you come to realize that drugs supplied by certain companies, the content in their capsules, the quality and quantity of medicine that you are prescribing are there. But you cannot be sure about a new pill by a new company that might be set up simply for making this particular type of pill for distribution and there is no real worry about them except making money. You say perhaps there is no real worry behind the larger companies except to make money.

The larger companies spend considerable amounts of money on research in drugs. A lot of these small outfits spend nothing on research. They may only have an office in their hat, and yet they distribute drugs they bring in from Italy or France and wonder why the general public don't accept them.

I think it would be very dangerous for doctors to accept some of these drugs that come in without having some standard of quality. If the Government at Ottawa [who] through their group are responsible for quality can say to the doctors, 'We are examining every batch of such and such a company's drugs and we find that it contains the ingredients and amount it is supposed to contain,' you won't ever find lack of acceptance of the lower priced drugs that you mentioned."

(Hearing, pp. 376-79)

(c) by Dr. James William Reid, medical practitioner in the City of Halifax:

"MR. WHITELEY: Dr. Reid, in prescribing by generic names have you found any difficulty in the quality of the product which is used to fill the prescription?

DR. REID: No, I haven't. To assess any difference in quality would be a rather long process, and mostly we work with the dispensing chemists as a partner, as it were, in the treatment of the sick. We expect him to use only good quality drugs in our prescriptions and, I think, by and large that is true. I think you can depend on that pretty thoroughly. I don't think any dispensing chemist would willingly, knowingly, put an inferior drug in a prescription of mine, and if he did put an inferior drug into it, it would be because he did not have access or methods of confirming the quality of the drug.

In other words that would have to go further back in its manufacture and inspection by checking, you see. Most of our druggists are completely qualified and ethical people who are using only the best quality chemical that they can."

(Hearing, p. 398)

(d) by Dr. John Patmore Gemmell, practising doctor and member of the staff of the Faculty of Medicine at the University of Manitoba:

"DR. GEMMELL: I will have to qualify this statement. The use of the generic name which is not an easy name, but in my experience it is becoming easier to remember generic names, but it is by no means a cure-all. . . .

. . . This goes to the pharmacist, and I have no assurance as to what brand of drug he will supply. It is then entirely in the pharmacist's hands.

THE CHAIRMAN: All he has is the generic name.

DR. GEMMELL: Yes, he may pick the most expensive one and charge accordingly. He may pick the cheapest one, on which he has no assurance that it is properly manufactured or anything. He may charge cheaper for the cheapest drug. For all I know, he may give the cheapest and charge the same as the most expensive. This completely removes from my hands any sort of quality care.

. . .

THE CHAIRMAN: But, generally speaking, would this be your position: if you were giving a prescription to a patient, for reasons of quality control you would tend to specify a trade name product of a manufacturer whom you considered to be reliable?

DR. GEMMELL: I would say this is only applicable in certain very critical drugs, and I think cortisone, persons whose life depends on an accurate dose level of this product. Otherwise, if you came to me for maybe a sleeping pill or antacid or aspirin, I am sure this is not at all critical."

(Hearing, pp. 526-30)

(e) by Dr. Mark Nickerson, Professor and Head of the Department of Pharmacology and Therapeutics at the University of Manitoba:

"THE CHAIRMAN: Doctor, is it your view that if the Food and Drug Directorate is able to put into operation the recommendations that have been submitted [see section 5 of Chapter VIII] that you could feel there is good quality control of all the drugs from small or large companies or companies abroad as well as those in Canada so that the generic names could be used more freely; that doctors would feel reasonably safe in using them.

DR. NICKERSON: This would be my hope and anticipation.

THE CHAIRMAN: That is one of the main purposes of this proposal?

DR. NICKERSON: Yes, that is the objective."

(Hearing, p. 562)

(f) by Dr. F.B. Rodman, Assistant Clinical Professor of Therapeutics at the University of Alberta:

"Now, also this question of generic names comes up, and it is not as simple to my mind as we are led to believe.

It is said that if a doctor writes a generic name, that his patient will receive a cheaper compound. I have

found that most of our pharmacists are only too happy to co-operate. I should not say most. As far as I am concerned, they all are happy to co-operate, but when you write a generic name you have no knowledge as to what preparation the patient receives. It then becomes the responsibility of the pharmacist to determine purity and source of supply.

Also, I find that the patient on one occasion will receive a white tablet, on another occasion a yellow tablet, and they come to me and say: 'I have not got the proper medicine. The druggist is no good'. So as the present arrangement stands, it means we must have prior arrangements with our pharmacist to have any idea what is being given. Certainly, if the preparation, if we could be sure that it was pure and packaged as expected in terms of weight, and as can be shown, studies have been made in the United States, there is considerable variation as to the drug contained in some of the preparations. If we could have an assurance that that was the case, then as a doctor we could do much to reduce the cost to our patients."

(Hearing, pp. 899-900)

As shown in the above quoted evidence, three physicians resort to brand names in prescribing certain drugs lest an inferior preparation be dispensed under a generic name. Dr. Reid, however, relies on the druggist to supply his clients with preparations of good quality, when he prescribes by generic name. It should also be pointed out that Dr. Reardon and Dr. Gemmell mention the fact that brand names are easier to remember than proper names.

8. Risks Inherent in the Use of Brand Names
and Informative Value of Generic
Terminology

The Merck Index of Chemicals and Drugs⁽¹⁾ contains the following information:

"Decortin. Caution: Decortin [E. Merck] is prednisone; Decortin [Schieffelin] is desoxycorticosterone acetate."

(1) The Merck Index of Chemicals and Drugs, Merck & Co. Inc., 7th ed., 1960, p. 322.

Moreover, the following excerpt from the brief presented by The Canadian Pharmaceutical Association, Inc. points out the similarity of some brand names:

" . . . Complexity and similarity of names may provide the pharmacist with an additional problem. For example, Preludin is an appetite depressant drug used in the management of obesity, but Proluton is an oral hormone product used in various female reproductive disturbances. Tensilone is a nitroglycerine and diuretic formula for use in high blood pressure, while Tensilon is a powerful antagonist of curare which, itself, is a very potent muscle relaxant. These are but two examples -- many more could be cited. . . ."

(Association brief, p. 77;
Hearing, pp. 2510-11)

These examples illustrate how the selection of brand names for drugs with closely similar spelling or pronunciation may lead to confusion. However, there is another aspect to the problem as it appears from a newspaper report of comments made before the Kefauver Committee by Dr. Walter Modell of Cornell University Medical College and reproduced in the Green Book (p. 23). According to these comments, the mere fact of using names that give no idea of the contents of the drug is confusing and dangerous. On this point, questions put to three experts appearing before the Commission brought the following answers:

(a) by Dr. N. Schechter, medical practitioner in the City of Ottawa and Chairman of the Pharmacy Committee of the Ottawa Civic Hospital:

"MR. CARIGNAN: Do you see any risk or danger in doctors prescribing by trade names only? . . . I understand that Dr. Modell teaches only the use of the so-called generic names. According to him, the generic name should be on all prescriptions.

DR. SCHECTER: Yes, while I don't really think that there is any great danger to use the trade names, I don't think a doctor will use a trade name drug unless he knows something about it. . . . but I do feel that if we concentrated more on generic names it would bring more order out of confusion.

We would have a generic name and we would know that this grouping of trade names belonged to this type of tranquilizers and it has these characteristic actions and side effects and toxic effects, and so on.

I don't know that there have been any accidents with the use of brand name products, from our staff. But I think that knowing drugs by their generic names is valuable to the doctor."

(Hearing, pp. 283-85)

(b) by Dr. J.P. Gemmell, Associate Professor, Faculty of Medicine, University of Manitoba:

"MR. MacLEOD: In connection with this matter of generic and trade names, the Director has included in his statement of material a quote which appears at page 23 saying that there may be some danger in the trade names. That is rather contrary to the position which you take. I would ask you to look at that, Doctor.

DR. GEMMELL: The doctor is Dr. Modell. I think if I may go back to my student's analysis [referred to in section 4 of Chapter XIV] about a fifth of them from the trade name you didn't know what was in the drug. I think it is very misleading. I think the doctor is neglecting his duty if he prescribes a drug and doesn't know what it is. Prescribing a drug without knowing what is in it is certainly not to be condoned, and the use of the trade name is to be frowned on if you don't know what is in it. Instead of using something like - I am just selecting at random - something like meticorten, that is prednisone, it is better to put prednisone."

(Hearing, p. 532)

(c) by Dr. Mark Nickerson, Professor and Head of the Department of Pharmacology and Therapeutics, Faculty of Medicine, University of Manitoba:

"MR. MacLEOD: Do you feel that there is any danger in the use of trade names along the direction he [Dr. Modell] indicates?

DR. NICKERSON: Yes, the point that he makes is that trade names often don't give any indication of what type of drug is involved, whereas the generic name in general gives some indication. I think this is a point, and

that it perhaps might be worthwhile to stress that if a person is going to, or does want the product of a particular manufacturer, there is more advantage in writing the generic name and then specifying the manufacturer or supplier. . . . a company has recently put out a new drug in the series, which . . . the previous example was phenylbutazone. This drug is quite effective in a number of rheumatoid states, but it is also quite a toxic drug. The trade name for this is Butazoladein; the generic name, phenylbutazone. The new derivative is hydrophenylbutazone, but the trade name is Teandril⁽¹⁾. I couldn't prove this point, but I suspect this is an attempt to get around many physicians' concern about the toxicity of the older drug. The generic name tells you immediately that this is almost the same thing. The trade name leads you to think it is not related in any way, nor does the promotional literature."

(Hearing, pp. 549-50)

(d) by Mr. J.L. Summers, Associate Professor of Pharmacy at the University of Saskatchewan and Director of Pharmaceutical Services at the University Hospital in Saskatoon:

"MR. MacLEOD: Does the use of the brand name create any difficulty?

PROF. SUMMERS: It creates confusion in that there is more than one name for a specific drug used, and unless you know that it is a brand name of a specific basic drug, sometimes you couldn't tell that the two brand names referred to a single therapeutic compound.

MR. MacLEOD: Is the brand name in that sense a source of confusion?

PROF. SUMMERS: It may be to some people. If you don't know, then certainly it confuses you, but if you do know your generic names and your brand names, you should not be too confused, no. If you do know.

MR. MacLEOD: The brand name of itself, as I understand it, frequently does not tell you anything about the nature of the drug?

PROF. SUMMERS: Yes, that is correct."

(Hearing, pp. 2268-69)

(1) These brand names appear to be misspelled. The correct spelling is Butazolidin and Tandearil.

"MR. MacLEOD: In respect to generic names then just what is your criticism?

PROF. SUMMERS: Well the general criticism is that the generic names are not easy to remember generally. They do not indicate the chemical group . . . to which the drug belongs, except in certain cases. May I use an example? One of the nicest examples of a group of drugs which is well-named generically are the tetracycline group of drugs. We have tetracycline itself, tetracycline hydrochloride. Then we have oxytetracycline hydrochloride. We have chlortetracycline and then we have demethylchlortetracycline and as each one has come out it has been a tetracycline and therefore we know that they are all of the same chemical genus and from a therapeutic point of view they should behave in a similar pattern. This, of course, we know does not necessarily follow.

PROF. SUMMERS: It is simply because it is of a certain pattern that we will obtain the same therapeutic response, we would expect a similar therapeutic response much more frequently when the drugs follow a pattern than when they don't.

MR. MacLEOD: What is your opinion about the generic names used in connection with the cortisone group?

PROF. SUMMERS: These have come along. We have cortisone, hydrocortisone, prednisone and prednisolone. After that we become a bit unstuck. We have triamcinolone. There is nothing in triamcinolone that normally you might refer it to the drugs from which it derives, the prednisones and the prednisolones or the basic steroids themselves.

MR. MacLEOD: What about the tranquilizers?

PROF. SUMMERS: The tranquilizers as a rule are not badly named. We do have some, for example, the drug meprobamate and carisoprodol. They are second cousins, but nothing in their terminology would tell us this."

(Hearing, pp. 2277-79)

"MR. MacLEOD: Will you agree with the comment in the green book or a statement of a doctor that is quoted in the green book where he says brand name, use of brand names has been carried to such an extent specialists in the same field may be talking about the same drug but not realize it?

PROF. SUMMERS: I have no competent knowledge of the drug knowledge of specialists. It may well be. I have no knowledge of it.

MR. MacLEOD: Have you any knowledge of confusion arising within your own experience by the use of brand names?

PROF. SUMMERS: Yes, but I also have just the same examples of confusion arising from generic names.

MR. MacLEOD: The same type of confusion?

PROF. SUMMERS: The same type of confusion.

MR. MacLEOD: Would you . . .

PROF. SUMMERS: One drug being mistaken for another because of similarity of sound or, at least, writing.

MR. MacLEOD: That is of the pharmacist interpreting the prescription?

PROF. SUMMERS: Yes."

(Hearing, pp. 2280-81)

9. Prescribing by Proper Names and Its Consequences for Pharmacists

Any preference on the part of a physician for proper names when prescribing for private patients outside of hospitals has no practical effect, if pharmacists fill with brand-named products even prescriptions written with proper names. For this reason, it is relevant to consider the behaviour of pharmacists with respect to non-proprietary prescriptions. As pointed out in section 4 of this chapter, the Drug Merchandising survey indicated that 62 per cent of the druggists fill a non-proprietary prescription with a brand-named product and 30 per cent with a generic preparation.

The attitude which retail pharmacists generally take toward the filling of prescriptions written with proper names and the effects of this attitude were described in the following sources of information:

(1) Brief presented on behalf of the Nova Scotia Pharmaceutical Society by its counsel, Mr. A.W. Cox:

" . . . He [the pharmacist] is required by law to dispense prescriptions exactly as the doctor orders. He has a choice in the matter only when the doctor prescribes the medicinal by its generic name. In such a case the pharmacist may dispense either a brand name drug, or a cheaper generic drug.

It is fair to say that at the present time pharmacists are reluctant to use some of the generic drugs prepared by little known or unknown manufacturers. They are not prepared to take unwarranted chances when the health of the public is concerned."

(Association brief, p. 3;
Hearing, pp. 467-68)

(2) Brief submitted on behalf of The Saskatchewan Pharmaceutical Association by its President, Mr. Alfred Pepper:

"Generic names are not in common use in this area. Most pharmacists would welcome the use of generic names where a product can be so prescribed because it could greatly reduce the number of products we are required to stock. In theory this would also reduce the price but for the present, would have little effect because pharmacists will not take the risk of supplying medication unless they are convinced of its purity and potency. . . ."

(Association brief, pp. 2-3;
Hearing, p. 797)

(3) Brief presented on behalf of The Alberta Pharmaceutical Association by its President, Mr. Walter Maday:

" . . . the inference that the pharmacists could immediately effect an appreciable saving by adding to their inventory a line of generic drugs is not accurate. Such a step would serve only to add greatly to the inventory of a drug store to accommodate a very small percentage of the prescriptions written in the light of present day experience. . . .

Should it be the policy of physicians to prescribe by generic terminology the retail pharmacists of Alberta would not be unhappy. They would wish it known, however, that they would not interpret this to mean that they were required to supply the cheapest. It is a fairly well recognized axiom that the cheapest is not necessarily the most economical. The choice being the pharmacist's he would probably choose to dispense a product which in his experience

had proven to be efficient, stable and competitive and had been manufactured by a firm whose integrity and reputation were beyond reproach. The individual pharmacist does not have the facilities necessary for testing and satisfying himself as to the standard and quality of drugs that might be available to him in Canada. Likewise, the Government of Canada cannot and does not purport to guarantee that all drugs will meet the quality and standards expected of them. . . .

. . .

It follows that the pharmacist must of necessity be forced to rely on those drugs which through experience he knows can be relied on to satisfy the requirements of safety and efficacy."

(Association brief, pp. 5-6;
Hearing, pp. 1010-12)

(4) Evidence given by Mr. Walter Maday, President of The Alberta Pharmaceutical Association:

"THE CHAIRMAN: . . . I take it from your submission your Association has no objection to the use of generic name drugs if you can be sure that they are [of] high quality and equal potency with drugs made by established companies using trade names?

MR. MADAY: That is right. It is of course difficult for individual pharmacists to establish themselves the product is good. He cannot travel east where the manufacture is carried out or where the distribution is carried out and inspect the plants. It is an awful outlay. We, as an Association, haven't guided pharmacists as to which products are good and which are not. It could well be that once a firm is known to be reliable then pharmacists will be very welcome to accept that as a known fact and when he dispenses he would know he would not be liable himself for giving out improper or inferior drugs."

(Hearing, p. 1025)

"MR. HUME: . . . If the law were changed the way it was suggested in the press so that if a product, a generic - a brand name is used which is a generic name and you were free as a pharmacist to fill that with any generic name drug you wanted, would you, as an experienced pharmacist, believe that would make very much difference to the way you fill prescriptions?

MR. MADAY: No sir.

. . .

MR. HUME: . . . If the law were changed, from your experience as a pharmacist filling prescriptions, would you think the percentage indicated by the survey would be much altered, from your experience?

MR. MADAY: No."

(Hearing, pp. 1081-82)

"MR. CARIGNAN: Mr. Maday, at page 6 of your brief it is said: 'The choice being the pharmacist's, he would probably choose to dispense a product which in his experience has proven to be efficient, stable and competitive, and had been manufactured by a firm whose integrity and reputation was beyond reproach'. In answer to a question from Mr. Hume, you said I think that even if the physicians had been obliged to prescribe by generic names, the percentages appearing at the foot of page 4 would not have been adequate [sic, altered]. You mean by that that 89% of prescriptions anyway would have been filled by using brand names? Does it mean that in your opinion the manufacturers of brand name products are more likely than the manufacturers of generic products to fulfil the canons set out in page 6, these canons being efficiency, stableness, competitiveness, integrity and good reputation. That is what you meant?

MR. MADAY: Yes, I am responsible for what I give out and if I would give out something of which I don't know, I would be liable for it, so therefore I have to give out the medication when ordered by generic name, I have to know it is good. My reputation is staked on it, so therefore I would turn to someone I know. . . .

. . .

MR. FRAWLEY: If it was marked: 'Canada approved', that would make all the difference in the world?

MR. MADAY: That would make a big difference. It would take it off my shoulders."

(Hearing, pp. 1103-04)

(5) Evidence given by Mr. Douglas Denholm, Registrar, The Pharmaceutical Association of the Province of British Columbia:

"MR. HUME: . . . It has been suggested from more than one source that there ought to be some requirement where doctors are required to write a prescription using the generic name only. My question is, if that came about, is it your view that the pharmacists in this Province would continue to use about the same proportion of brand name as opposed to generic name drugs as they do now?

MR. DENHOLM: . . . I would hesitate to say whether this would make any difference to the dispensing habits of the pharmacist.

. . .

THE CHAIRMAN: . . . if doctors were required to prescribe by generic name, and if the pharmacist is satisfied in his own mind that a certain drug which is prescribed is manufactured with proper quality control measures, would he have any hesitation in supplying that drug, rather than one sold under a trade name?

MR. DENHOLM: None whatsoever. The prime point is your reference to the quality of the drug. This must be the pharmacist's first consideration. Once this consideration has been satisfied, then there is no further requirement sir."

(Hearing, pp. 1206-08)

(6) Brief submitted on behalf of The Canadian Pharmaceutical Association, Inc. by its General Manager and Secretary-Treasurer, Mr. J.C. Turnbull:

"From the physicians's viewpoint, brand names and brand-named products undoubtedly have certain advantages, including (1) relatively easy to remember, (2) relative quality is known, (3) usually associate name with a company, (4) recall to mind distinctive physical properties, and (5) use assures that exactly the same product is supplied to his patients or to the same patient at different times. To the pharmacist, the same factors are advantageous, although prescribing by chemical or common name designations which permit dispensing of known, reliable brands or non-brands, would enable him to better utilize his own professional training and, at the same time, permit him to carry a less extensive inventory."

(Association brief, p. 41;
Hearing, p. 2401)

From the evidence quoted above, it appears that the stocking by retail pharmacists of a wide range of generic preparations may result, under present conditions, in additions to their inventories which would be economically unjustified in view of the small percentage of non-proprietary prescriptions. If the practice of prescribing by proper names were generalized or if in all Canadian provinces pharmacists were permitted under circumstances determined by law to substitute a pharmaceutical equivalent to a brand-named preparation appearing in a prescription, then retail pharmacists would be in a position to utilize better their professional knowledge and to reduce their inventories. To what extent this development would tend to increase the proportion of prescriptions actually filled with generic preparations is difficult to estimate in view of the fact that pharmacists are reluctant to dispense the products of little known or unknown manufacturers. However, there is no doubt that this proportion would be increased, if druggists believed they could rely on the quality of a wide range of products marketed under proper or generic name.

CHAPTER XXIV

THE PRESCRIBING PHYSICIAN AND THE COST OF MEDICATION TO THE PATIENT

1. Ways in which Physicians may Help to Reduce the Cost of Medication

While prescribing by generic or brand name has a bearing on the cost of medication, it appears from the evidence analysed in the previous chapter that many doctors avoid prescribing by non-proprietary terminology lest a drug of inferior quality be dispensed by the pharmacist. To a limited extent however, a physician may help his patients to save money without any risk of impairing the value of the treatment administered to them. For instance, whenever two or more preparations are equal in their treatment value, the low-priced pharmaceutical may be advantageously prescribed. Worth-while economies may result from not prescribing either excessively "elegant" medicines which have satisfactory simpler equivalents sufficiently well suited to the requirements of a particular patient or unnecessarily elaborate polypharmaceutical preparations which have no therapeutic justification in relation to the patient's needs. Moreover, whenever the appropriate drug may be bought over-the-counter and no placebo effect is expected from prescribing, the amount of the professional fee usually charged by pharmacists may be saved by the patients, if they are properly advised by their doctors.

With respect to good and economical prescribing, the Final Report of the Hinchliffe Committee to the British Minister of Health gives the following advice to practitioners:

"(xxix) Doctors should not prescribe expensive, elegant preparations when simpler preparations of the same drug are available.

(xxx) Doctors should refrain from prescribing unnecessarily elaborate polypharmaceutical preparations.

(xxxi) Information should be supplied about prices of B.N.F. [British National Formulary] and analogous preparations, classified by therapeutic groups and, wherever practicable, doctors should select from the appropriate group the least expensive of the effective drugs available.

(xxxii) There should be no ban on the prescribing of new drugs, but until the results of clinical trials are known, doctors should only prescribe new drugs when existing drugs have failed."⁽¹⁾

With respect to amount of drugs to be supplied on one prescription under the British National Health Service, the report referred to above contains the following:

"295. . . The selection of the drug most suitable for treating a patient and the appropriate dosage is a very different matter from the assessment of the quantity to be made available on each prescription. In the case of private patients the cost of the prescribed drugs is likely to affect the quantity ordered on each occasion. But in the case of drugs prescribed in the National Health Service this consideration does not apply: indeed, so far as some patients are concerned, 'the more the better'.

We believe that doctors might welcome a regulation which enabled them to say to an importunate patient, 'The maximum amount permitted on one prescription is so much'.

296. The Committee which reported to the New Zealand Minister of Health in May 1957 on measures to affect economies in the cost of pharmaceutical benefits recommended that the amount permitted to be ordered on any one prescription should be restricted to ten days' supply. In addition, one similar repeat would be permissible. In 1954 the New Zealand authorities had introduced a restriction on the maximum quantity to be ordered at one time and limited this to an amount necessary for fifteen days' treatment, with the possibility of one repeat. This measure, according to the report, considerably reduced the average cost of prescriptions.

(1)

Great Britain, Ministry of Health, Final Report of the Committee on Cost of Prescribing, Her Majesty's Stationery Office, London, 1959, p.8.

It is interesting to note that this restraint on quantity was considered worthwhile as far back as 1954 and that the New Zealand Committee felt justified by the results in recommending that the same procedure should be even more stringently applied.

. . .

298. It should be possible to reach an agreement with the medical profession that the amount of drugs supplied on one prescription should be limited either to that required for the patient's illness, if it be expected to last less than seven days, or to not more than one week's supply, with exceptions for chronic or particular cases. There are so many variable factors that it would be difficult or impossible to devise any effective regulation. Some courses of treatment last for five days only; others for twelve. The dosage of a particular drug varies greatly for different diseases and this applies in particular to the expensive antibiotics and steroids. It must be remembered, too, that practitioners generally have to see their patients at weekly intervals for purposes of certification and it is convenient to them to issue prescriptions at the same intervals.

After the first two weeks the aim should be to prescribe no more than a fortnight's supply at any one time except in long-term cases such as diabetes, epilepsy, asthma, chronic bronchitis, etc., when a special mark such as an asterisk could be added to the E.C. 10 [form] ." (1)

With respect to the assessment of the quantity of drug to be made available on each prescription, there is some difference in approach between the above recommendation by the Hinchliffe Committee and the practice under the Medicare Plan in the province of Manitoba, as appears from the following evidence given by Mr. J. W. Richardson, Vice-President of The Manitoba Pharmaceutical Association:

"The Provincial Government has suggested that where feasible, and possible, that the physician write a prescription, prescribe for a month's quantity of a medication, if it is thought

(1)

Ibid., pp. 91-2.

that the patient is to require a month's supply of that medication, with the result that we are receiving larger prescriptions, that is prescriptions for larger quantities than the physician would normally write for a non-Medicare patient. A non-Medicare patient may not have the cash, or may not be willing to take a month's supply of some medication. They are satisfied with a week or two weeks' supply. Now, the Government is trying to eliminate a certain amount of expense by asking the physicians, where possible, to prescribe a larger quantity, . . .

THE CHAIRMAN: The average quantity of the Medicare prescription being larger, the price per prescription will be higher, though the cost for doses may even be lower?

MR. RICHARDSON: That is right, sir. On our method for pricing, if we dispense two lots of 50, the price for the two lots would be higher than the price for one lot of a 100, so this has given the impression of a higher unit price per prescription, higher than the consumer would normally buy."

(Hearing, pp.629-30)

If we compare these two approaches to the problem, the first leans toward small quantities per prescription in order to cut down expenses, where a certain number of doses is expected to effect a cure, while the second leans in favour of larger quantities in order to cut down the number of prescriptions and perhaps avoid some payments of druggists prescription fees, where long continued treatment is necessary. Thus, while the two approaches differ, the views of the Hinchliffe Committee and those of the Manitoba governmental authorities may be said to be more complementary than contradictory as in each case different types of circumstances were being considered.

Finally the prescribing physician's inability under the medical profession's code of ethics to direct the patient to a particular drug store because it offers drugs for sale at lower prices than other pharmacies was pointed out to the Commission by Mr. Douglas Denholm, Registrar of The Pharmaceutical Association of the Province of British Columbia:

"MR. MACLEOD: Do you consider or does the Association consider it unethical to have a doctor suggest to a patient that a patient have this prescription filled at a particular drug store because that drug store is selling more cheaply?

MR. DENHOLM: Well, sir, it is not the function nor the position of the Association of Pharmacists to comment on the ethics of physicians. This is a function which is undertaken by the College of Physicians and Surgeons and I believe that in fact one

section of their Act specifies that referral to a specific drug store or the use of prescriptions with a drug store name on it constitutes unethical conduct, but that is not a matter for decision by the pharmacists.

MR. MACLEOD: Do you know if in British Columbia the practice of doctors prescribing [sic] with the name of the drug store on top?

DR. DENHOLM: On one or two occasions such a practice has been drawn to our attention.

MR. MACLEOD: What have you done about it?

MR. DENHOLM: We have indicated to the pharmacist involved that it is our understanding of the Medical Act that the use of such prescription by a physician constitutes an unethical practice as far as they are concerned and drawing it to their attention.

MR. MACLEOD: Have you also drawn to the attention of the Medical Association the fact a doctor or certain doctors were recommending their patients get prescriptions filled at certain drug stores because prices at those drug stores were cheaper?

. . .

MR. DENHOLM: With the exclusion of because prices at those drug stores were cheaper, yes sir. We have on occasion when it has been reported to us and on what we believed to be a substantial grounds that such a recommendation has been made when a physician has recommended to a patient that he go to a specific drug store for whatever reason. The reason is of little interest to us. We have raised the matter with the proper medical authority because it is not our province to comment to the physician on these matters."

(Hearing, pp.1283-85)

2. Sources of Information Available to Doctors with Respect to the Cost of Drugs

As indicated by Dr. J. P. Gemmell in an excerpt from his evidence quoted in section 4 of Chapter XIV, a fourth-year student at the University of Manitoba made a study of the direct mail advertising received by the physicians attached to the Department of Clinical Investigation of the Winnipeg General Hospital and this study shows that in 95% of cases the materials received did not contain any information on the cost of the drug to the patient.

In this respect, the brief of the Canadian Pharmaceutical Manufacturers Association stated:

"Furthermore, it was inferred 'that in 95% of cases absolutely no information is available on the cost of the drug to the patient'. Dr. Nathan Schecter said in Ottawa before this Commission that detail men will often quote the price. Any detail man will tell you that one of the questions asked by a doctor on the introduction of a new product, is how much does that product cost. Price is not generally included in medical literature, for the simple reason that this literature goes to doctors from coast to coast. To do this, the manufacturer would have to use his suggested list price which might not be the final price in all areas depending upon differences in prescription fees, the variances in the retailers' overhead in different areas, and similar factors. However, the detail man is quite prepared to discuss the price of his products with the doctor at any time."

(C.Ph.M.A. brief, pp.70-71; Hearing, p.1969)

On the role of detail men in advising doctors about prices, Mr. Conder was corroborated as follows by Mr. R. B. Thompson, Manager of the Medical Products Department of Cyanamid of Canada Limited:

"THE CHAIRMAN: We have had some evidence from some doctors that they are not familiar with the prices of the drugs. They are concerned primarily about what the effects will be on the patient. Some others have said they know fairly well what the prices are. I was wondering what the practice of your detail men was, to tell them what the price was so they would know when they are dealing with patients they realize have very little money to spare, whether the prescription

he is proposing is going to be a very serious burden or not.

MR. THOMPSON: Indeed, Mr. Chairman, our men are expected to discuss price whenever the question is asked and further, in some cases, suggest the most economical size of prescription for the patient. The package is generally geared also, for example, one of our packages contains 28 tablets, which is one week's supply. This is done because it is the most economical way of getting that package to the consumer through the hands of the retail pharmacists."

(Hearing, pp.1499-1500)

In the evidence before the Commission four practising doctors described as follows the source of their information with respect to the prices of drugs:

(a) Dr. Nathan Schechter, medical practitioner in the City of Ottawa and Chairman of the Pharmacy Committee of the Ottawa Civic Hospital:

"THE CHAIRMAN: Do the detail men who come to your office describing the drugs give you any indication what the retail price might be?

DR. SCHECTER: Yes, they often will quote the price. We will ask them about price of a certain article.

THE CHAIRMAN: This literature which comes with it, promotion literature, promotion content, that sort of thing?

DR. SCHECTER: No, they don't have drug prices on.

THE CHAIRMAN: So far as the advertising promotional matter is concerned you only get a fragment of that information?

DR. SCHECTER: Yes.

THE CHAIRMAN: Of what you need for good judgment.

DR. SCHECTER: And the manufacturers price and the retail pharmacist price can be quite different.

THE CHAIRMAN: Oh yes, that is true. That is true.

DR. SCHECTER: So that doesn't give us a final answer."

(Hearing, pp.267-68)

(b) Dr. Mark Nickerson, Professor and Head of the Department of Pharmacology and Therapeutics at the Faculty of Medicine of the University of Manitoba:

" . . . You can obtain it [the price] from detail men. If you write away or have the initiative to write to the pharmaceutical houses I think most of them or all of them have a little catalogue which lists their prices. Doctors ordinarily do not have these available, in my experience, . . ."

(Hearing, p.544)

(c) Dr. J.P. Gemmell, Associate Professor at the Faculty of Medicine of the University of Manitoba:

" . . . Also I am sure most doctors will certainly ask the detail men about the cost of this material.

THE CHAIRMAN: Is it your experience most doctors do ask for the cost? Do you mean the cost to the consumer?

DR. GEMMELL: That is right. He will ask it from the detail men. It is not available in any -- well, I don't think - it is almost - it is just not available. If you can find examples as to what the cost of the drug or the suggested retail price is in this material there, outside of a few advertisements in the Lancet - this is not available to the doctor and the only way that the doctor, with the multitude of drugs, as you are well aware, before writing the prescription, can find out the cost is to go to the trouble of going to the pharmacist, if he knows the pharmacist that the person is going to go to and ask him what he is going to charge for this.

. . .

MR. WHITELEY: These catalogues, which you gave us, are examples of literary articles that are sent out by the manufacturers to doctors?

DR. GEMMELL: In my experience it is only - if you want for the sake of a name, the generic-named ones are the only ones that deliberately send the catalogues because this is, of course, a selling point in their promotion. Many of them - I don't know whether that does - will contain certain comparative prices in here but there is no one single book that I can look at. If I would like a drug by the generic name or by the trade name, there is no book that I can look up to see what it costs the patient - none.

THE CHAIRMAN: The costs might vary a little bit because the druggists charge a little different prices?

DR. GEMMELL: Yes, it may even vary from manufacturer to manufacturer."

(Hearing, pp.514-16)

(d) Dr. F.B. Rodman, Assistant Clinical Professor of Therapeutics at the University of Alberta:

"MR. MACLEOD: Is it difficult for a doctor to keep up with the cost of drugs?

DR. RODMAN: Well, it was difficult until I started the small card index system that I have in my righthand drawer. Each new product that comes in I ask the price to the patient, and I note it down on the card. If I am in doubt I 'phone one of my pharmacist friends and find out about the product or its equivalent that might be cheaper.

MR. MACLEOD: Of course you go to a great deal of trouble to maintain this system?

DR. RODMAN: No, it is no trouble. When the individual comes to see me they all have a card. It is a simple matter to jot the price down and file it in its place."

(Hearing, pp.907-08)

From the foregoing, it appears that except with respect to the products of the generic firms, physicians who want to get acquainted with either the prices charged by drug manufacturers or suggested by them for resale, have to inquire from the manufacturers directly or through their detail men. Moreover there is no other way for them to know the precise price charged a particular patient for a given drug than by inquiring from him or from the pharmacist who is dispensing the drug to him.

With a view to advising medical practitioners on good and economical prescribing, the British Columbia Division of the Canadian Medical Association has taken an initiative which to the knowledge of the Commission is unique in Canada. It has appointed a committee to study the cost of various drugs and, if possible, their relative treatment value. In August, 1960, this committee started to publish in the British Columbia Medical Journal a series of articles on the cost of various drug therapies. Up to this date four articles have appeared. They dealt respectively with the cost of asthma, gastrointestinal, corticosteroid and vitamin therapy. Other articles are expected to be published in the future. (1)

In Great Britain, the Interim Report of the Hinchliffe Committee contains inter alia the following recommendations aimed at providing practitioners with more adequate information on the cost of drug therapy:

". . .

(ii) The Minister should confer with the British Medical Association and the Pharmaceutical Society with a view to the production of a comprehensive prescribing handbook which should include information about comparative costs of standard drugs and proprietary preparations;

(iii) The law should be amended, if necessary, to compel manufacturers to indicate in literature circulated to doctors the retail price of the advertised product;

. . .

(v) 'Prescribers' Notes' should be circulated to all clinical teachers, consultants, hospital doctors and final year students as well as to general practitioners. The Notes should be issued more frequently and should be expanded

(1)

This information was conveyed to the Commission in a letter dated August 6, 1962, from Mr. J. H. MacDermot, M.D., Editor-in-chief of the British Columbia Medical Journal. The articles referred to above are reproduced in extenso in Appendices K, L, M and N to this Report.

in scope;" (1)

The "Prescribers' Notes" referred to above is a circular that the British Ministry of Health has been publishing for some years and which offers detailed guidance on the cost of drugs in current use. About this publication the Final Report of the Hinchliffe Committee contains the following information:

"36. Prescribers' Notes: When the National Insurance medical benefit arrangements were in operation, doctors' representatives (through the Insurance Acts Committee of the British Medical Association) issued a memorandum showing doctors how they could prescribe effectively without undue cost.

It was thought that it would be helpful to doctors in the general practitioner service of the National Health Service if occasional Notes were prepared to bring to their notice information which might assist them to prescribe economically. After consultation with the profession the first set of 'Prescribers' Notes' was prepared and sent to doctors in February, 1952. By the end of 1958, 24 issues had been made altogether. The main object of the Notes has been to bring to doctors' notice such points as the limitations of the uses of expensive new drugs (as advised in technical journals), other published clinical information about the cost of effective prescribing and economical packs of dressings.

. . . .

160. We regard the provision of adequate information, together with the improvements in training and education which we have recommended in the preceding section of our report, as the key to good prescribing. Indeed this appears to us to be the only alternative to some form of restriction for ensuring economy as well as efficiency in prescribing. What the general practitioner needs above all in this context is

- (i) a critical and unbiassed statement of the advantages of new drugs compared with existing products; and
- (ii) information on the cost of treatment compared with that using existing products whether proprietary or standard.

(1)

Great Britain, Ministry of Health, Interim Report of the Committee on Cost of Prescribing, Her Majesty's Stationery Office, London, 1958, p.11.

This latter information is not difficult to obtain and our interim report indicated our views on how it should be provided, e.g. through the medium of a comprehensive prescribing handbook. Whatever form the new handbook takes, it is clear to us that something more is needed to provide the information at (i) above. This information is usually difficult to obtain especially in the early stages of a product's existence.

. . .

162. In our interim report we made various suggestions with regard to the expansion and wider circulation of Prescribers' Notes. Since taking further evidence it has become clear to us that many doctors tend to regard the Notes as not presenting a sufficiently independent point of view. For this and other reasons we have come to the conclusion that Prescribers' Notes, in spite of its undoubted usefulness, is not an adequate or suitable channel for conveying to doctors information of the sort we think they really need." (1)

3. Concern of Physicians About the Cost of Drugs

The purchase of prescription drugs is peculiar in that the person who prescribes or orders them is not the one who pays for them. It was therefore material to inquire to what extent physicians have knowledge of drug costs and are influenced by them in prescribing. Questions put with respect to this matter brought out the following answers from five practising doctors:

(a) from Dr. Nathan Schechter, medical practitioner in the City of Ottawa and Chairman of the Pharmacy Committee of the Ottawa Civic Hospital:

(1)

Final Report of the Committee on the Cost of Prescribing,
pp.18-19; 50-51.

"THE CHAIRMAN: . . . Does your experience enable you to say whether doctors generally, if they find a patient has a condition for which two or more drugs may be approximately equal in their treatment value, judge between them, pay some attention to the economic situation, the cost? Can you answer that sort of question?

DR. SCHECTER: Do we pay attention?

THE CHAIRMAN: Are doctors generally in a position that they can make a decision with that in mind generally?

DR. SCHECTER: Not generally, no. We don't know enough about drug costs and there is some variation in retail druggist charges from druggist to druggist."

(Hearing, p.267)

"MR. FRAWLEY: . . . Is it the doctor's business , or considered to be the doctor's business, to keep himself really well informed about the price that has to be paid for these drugs?

DR. SCHECTER: No, I don't think it is the doctor's business to. . . .

. . .

DR. SCHECTER: We do concern ourselves with this hormone microzone [dexamethasone], which patients require a long time. We are not concerned about something which will clear a situation up in about 16 capsules, which a patient pays ten or twelve dollars for."

(Hearing, pp.279-80)

(b) from Dr. Charles Henry Reardon, medical practitioner in the City of Halifax and member of the Legislative Assembly of Nova Scotia:

"MR. MACLEOD: I take it that you do concern yourself with the question of price that your patient is going to have to pay?

DR. REARDON: Certainly.

MR. MACLEOD: And try to keep it as reasonable as possible?

DR. REARDON: Yes. We have no control over price.

. . .

. . . The prime consideration in drugs, to my point of view, is to see that the drug will do the job that you want it to do. Price is not the prime consideration. The prime consideration is getting the patient better. After that the price must come into it, but the prime consideration is to see that the patient gets the drug that will cure that patient for that particular disease."

(Hearing, pp.375-77)

(c) from Dr. James William Reid, medical practitioner in the City of Halifax:

"MR. MACLEOD: Do you keep in touch with the costs of particular drugs, what they are going to cost your patient when you prescribe a particular drug?

DR. REID: No, I don't dare do that because if I knew what the cost of the drug was, I might not prescribe it. So that, generally speaking I don't look very closely at the cost of drugs.

There are a few exceptions to that, mostly the expensive cortisones. We are very acutely aware of the cost of them but I would not dare allow the cost of drugs to interfere with my prescribing. That would be unsound.

MR. MACLEOD: Your principal concern, Doctor, is that the medicine should be the best one for the particular condition, rather than any question of what it costs?

DR. REID: Yes. That it might be high in cost is unfortunate, and I must say that we do become familiar with the cost of a drug as time goes on, and it does cause us a little thought, perhaps, but it does not interfere with prescribing.

If I think the patient requires a drug, I order it, regardless of cost and mostly that does not work too much hardship, I don't think, on the patient because many of the higher cost drugs are for very brief use. Again, there are expensive drugs such as cortisone and a few other things, but most of the high-cost drugs and certainly the early ones, the antibiotics as we call them were for very short time use and the total cost on a year's budget for a family did not amount to too much, actually."

(Hearing, pp.391-92)

(d) from Dr. Mark Nickerson, Professor and Head of the Department of Pharmacology and Therapeutics at the Faculty of Medicine of the University of Manitoba:

"MR. MACLEOD: Now, another point which Dr. Gemmell suggested we raise with you is the sources of information for doctors. I think he was speaking particularly about the information about list prices and cost to the patient. Can you tell us something about that, Doctor?

DR. NICKERSON: Well, it is my experience that by and large doctors do not know unless it is a drug they have prescribed quite regularly over a period of time - do not really have an appreciation of what the price is. . . I know about one or two instances in which the patient almost committed double mayhem on the pharmacist and doctor because a prescription was written and the doctor had read something about a new preparation and did not realise that a two weeks' supply he was ordering for the patient cost something in the neighbourhood of \$50.

When the patient got this small box and the request for the money, I think he almost tore up the drug store, so that this is a very real problem.

I think that a great deal can be said for requiring some indication of prices or recommended prices on a drug, I would very much like to see something like that."

(Hearing, pp.544-45)

(e) from Dr. J.D. Ross, Minister of Health, Province of Alberta:

"DR. ROSS: . . .

I feel, sir, that having been a practising physician for many years myself doctors have a responsibility to consider the economic status of their patient when they are considering the treatment that is in the best interest of the patient, and we feel that, although most medical men do feel this way, sir, I am sure that there are some who do not give as much thought to it perhaps as they should, which results in a considerable load of expense being carried by their patients which may otherwise be relieved.

THE CHAIRMAN: It is sometimes said that doctors very commonly have no real knowledge of the price the patients may have to pay, and if that is the case it is rather difficult for them to distinguish.

DR. ROSS: That is correct."

(Hearing, pp.867-68)

(f) from Dr. F.B. Rodman, Assistant Clinical Professor of Therapeutics at the University of Alberta:

"DR. RODMAN: Mr. Chairman, gentlemen, the practising internist is faced with a problem these days and that, let me say, if I may, that we are not blind to the picture, we see both sides, and what I attempt to do myself when a new compound is marketed is I note it, I put the price on a little card and put it in a drawer, and where certain selective cases come along I use it. But by and large I find more and more I am tending to stay with the standard drugs of which I know the action and where the cost is less. Similarly, in these thiazide drugs where they happen to be the ones under discussion, the new ones have shown possible promise in the new work. Again I have learned as an internist in Western Canada I am better to take my time and let the large centres in Eastern Canada work it out and let the literature give me the advice I need. Where the treatment is short the cost is not of great significance, but where there is a heart condition the price is important and it behoves one to consider the cost of the drug.

So that, sir, is my position. I am not anxious to rush into the widespread use of new drugs as they come on the market; I prefer to stay with the ones that I know and pass on the cost-saving.

. . .

If I might deviate, namely, in the position of the practising doctor as to what he can do to try and help his patients. Now primarily I think his thoughts must be, one, that the drug has the action that he wishes; two, that it is safe for his patient, I think, then, there are no exceptions that cost must be secondary to those two primary conditions. So to my mind when I see a drug quoted at a much lower price the question raises itself to me: Where did it come from? Who made it? Who packaged it? Does the drug dissolve? Does it go through the internal tract, and does it break up into half-package instead of the original quantity? And I would like to know and

have the assurance that the preparation I am using is satisfactory."

(Hearing, pp.896-99)

It appears from the foregoing that in most cases physicians do not know at what prices the drugs they have prescribed are sold to their patients. Their prime consideration, when prescribing, is to select the best drug for the particular condition of their patient. But they show some concern about the cost of medication at least when highly expensive drugs are prescribed for a long period of time. Moreover it should be recalled that, according to excerpts from Dr. Schechter's and Dr. Rodman's evidence quoted in section 3 of the preceding chapter, medical practitioners are becoming increasingly concerned about the cost of medication due to the publicity recently given to this matter.

4. Instruction of Students and Practitioners in Costs of Drugs

Doctor F.B. Rodman, Assistant Clinical Professor of Therapeutics at the University of Alberta, said that the problem of cost has a part in every drug discussion that he has with his students. However the evidence before the Commission does not reveal to what extent this practice is general in Canadian universities.

With respect to medical training, the Final Report of the Hinchliffe Committee contains inter alia the following findings, conclusions and recommendations:

"(viii) While it is not expedient to make statutory provision for a compulsory examination in costs as part of the medical curriculum, all medical schools should be encouraged to take an interest in economy in prescribing. The attention of all teaching bodies should be drawn to measures designed to impress on students the importance of economical prescribing.

. . .

(xv) Deans and Directors should be asked, where appropriate, to consider including in the syllabus for refresher courses instruction about advances in practical therapeutics and the merits and demerits of new drugs and some indication of costs." (1)

(1)

Ibid., p.6.

CHAPTER XXV

USE OF PROPER OR BRAND NAMES IN PRESCRIBING BY MEMBERS OF HOSPITALS' MEDICAL STAFFS

1. Hospitals' Policies with Respect to the Use of Proper and Brand Names in Prescribing

When attached to a hospital, doctors may not show the same preference for brand names as when prescribing for patients outside hospitals. Indeed some hospitals try to influence their behaviour by advocating the use of proper names, as appears from the following evidence from:

(1) Dr. Nathan Schechter, practising physician in the City of Ottawa and Chairman of the Pharmacy Committee of the Ottawa Civic Hospital:

"DR. SCHECTER: . . . We have been trying at our hospital to introduce the ordering of drugs by generic names.

MR. MacLEOD: May I just stop you there, doctor, and get that clear. When you say 'In our hospital ordering drugs by generic names', does that mean the hospital ordering them or the individual doctor?

DR. SCHECTER: The doctor ordering them.

MR. MacLEOD: The individual doctor ordering them by generic names?

DR. SCHECTER: Yes. . . .

. . . .

DR. SCHECTER: . . . it is our desire to have the staff order by the generic name.

MR. MacLEOD: Perhaps you would say something of your reasons for that, Doctor, if you would, the generic and brand name question.

. . .

DR. SCHECTER: The thing is that if one learns the generic name for drugs one does not have to learn all the duplications, all the various brand name products."

(Hearing, pp. 256-60)

(2) Dr. C.C. Misener, medical administrative assistant to the Director General of Treatment Services, Department of Veterans Affairs:

"DR. MISENER: I am Secretary of the Departmental Pharmaceutical Committee.

MR. MacLEOD: Secretary of the Departmental Pharmaceutical Committee. With what problems is that Committee concerned?

DR. MISENER: It is comprised of all the Chiefs of Service (Medicine) in our Departmental Hospitals across Canada and they advise the Director General of Treatment Services on all technical and professional matters relating to drugs used or paid for by the Department.

. . .

DR. MISENER: . . . They consider it is good medicine to encourage the prescribing of drugs and requisitioning by generic name."

(Hearing, pp. 329-30)

Whether the medical practitioners attached to a hospital prescribe by brand or proper names, their choice has no practical consequence at least in hospitals where the formulary system prevails, as will be shown in the next section.

2. Description of the Formulary System

The Formulary System in use in many Canadian hospitals is described as follows in a brief presented by Professor J. L. Summers of the University of Saskatchewan on behalf of the Canadian Society of Hospital Pharmacists:

"Under the Formulary System, a medical staff member agrees that when he prescribes by proprietary name the pharmacist is authorized to dispense the same drug under its non-proprietary name, irrespective of whether it is or is not of the same brand referred to in the prescription or order. In effect the medical staff of the hospital authorizes the hospital pharmacist to exercise his professional judgment in the selection of the suppliers of the drugs dispensed.

In order to better understand the principles involved, definition of terms indicates that:

1. The Hospital Formulary System is the method by which the medical staff, through the Pharmacy and Therapeutics Committee, studies and selects drugs which they consider are the most useful for the treatment of the patients.
2. The Pharmacy and Therapeutics Committee is a committee of the medical staff which represents the official line of communication and liaison between the medical staff and the pharmacy department. It is generally composed of the hospital pharmacist and physicians appointed by the medical staff. The discussions and recommendations of this Committee are approved by the medical staff and the administrative authorities of the hospital before they are implemented in the hospital.

. . . .

In establishing a Formulary system in a hospital, it is essential that the consent of each person authorized to write a prescription be obtained. This may be done by:

1. Incorporating the basic policies in the medical staff by-laws; or rules and regulations,

2. Obtaining separate documents from each physician, or
3. Having a statement printed on each prescription form.

Certain principles necessary to the functioning of the system include written policies and procedures, and provisions for the use of drugs not included in the formulary, and provisions for the control and use of investigational drugs. The pharmacist, under the guidance of the Pharmacy and Therapeutics Committee, is responsible for specifications as to the quantity, the quality and the source of supply of all drugs, chemicals, biologicals and pharmaceutical preparations."

(C.S.H.P. brief, pp. 6-8;
Hearing, pp. 2216-20)

A Hospital Formulary or Drug List is a compendium of drugs which reflects the clinical judgment of the medical staff of the institution.

With respect to this matter, the brief presented by the Canadian Hospital Association contains the following information:

"... the medical staff by their treatment orders and prescriptions determine what drugs are to be provided and it has been established that eventually a pharmacy stock list is developed and is written down as an inventory. In a number of instances an attempt has been made to stabilize this list by securing some authority other than the individual physician or pharmacist to determine what additions or deletions may be made. This then may be the beginning of what is termed a formulary.

The Pharmacy and Therapeutics Committee . . . is the group normally giving direction to such a project. In practice, the committee studies and grades the effectiveness of pharmaceuticals on the list using as a matter of principle that what is most effective is likely to be the cheapest in the treatment of the patient. The committee then decides what items are to be included in the formulary and to this end may set up certain rules about the admission of new drugs. Frequent revision is necessary and individual staff members may make representation to the committee regarding the inclusion of any item he may wish to see in it.

Fully developed formularies usually contain such items as a list of products by their official name in English, together with a description of their properties, chemical structure, dosage forms, and stock sizes. Indexing is very important and products may appear in alphabetical order within groupings according to therapeutic use. In hospitals with extensive specialization among medical staff, such groupings could be by medical departments for ease of reference. Cross-indexing to terminology commonly used for certain products by the medical staff contribute to the practicality of such a formulary."

(Association brief, pp. 9-10;
Hearing, pp. 1751-54)

Asked whether or not pharmaceutical compounds are included in the formularies, Professor J.L. Summers explained as follows how this problem was dealt with at the University Hospital in Saskatoon:

"We list the single drugs. For example, we list the drug codeine. Under codeine are listed all of the preparations which we have in stock which contain the drug codeine, and the actual additional ingredient, for example, A.P.C. with codeine would actually be spelled out as to the individual drugs that were contained in the preparation."

(Hearing, p. 2270)

Under the Formulary System, the physician still determines not only the drug that will be dispensed, but the route of administration and the appropriate dosage form. However, with respect to the brand, his choice may be restricted to a certain extent. With respect to this matter, the following evidence was given by

(1) Dr. C.C. Misener:

"... off list drugs in large numbers are used in our hospital. When first obtaining an off list drug the Chief of Service (Medicine) has to write a letter stating its composition and its therapeutic effect and why he needs it. He countersigns a requisition. That letter accompanies the requisition to the Head Office. They come over my desk. When he says he needs that drug, of course it is supplied."

(Hearing, p. 333)

(2) Professor J.L. Summers:

"THE CHAIRMAN: We have had some representations that although a drug, the basic drug in a preparation, may be the same, when it is made by several different companies and sold under trade names there are differences in the dosage itself, in the way it acts and reacts on the patient. Have you any problems of that kind?

PROF. SUMMERS: No, sir. I feel these are things where the hospital pharmacist is expected to exercise professional judgment. If he can't do this, he should not be a professional pharmacist.

THE CHAIRMAN: A doctor may prescribe a drug made by Ayerst, and another one may prescribe one by Cyanamid or Upjohn because he thinks it will act a little bit differently.

PROF. SUMMERS: In the formulary system there is provision for this thing, for this type of problem. If the physician believes that such a drug in fact is more clinically effective and can present conclusive evidence to the Pharmacy-Therapeutics Committee that it in fact does do so, then he may request that this drug be brought in.

THE CHAIRMAN: It is not simply at his request; it is on production of proof to satisfy the Committee that for the particular purpose he has in mind one particular brand name drug is more suitable to get the desired result?

PROF. SUMMERS: This is normally taken care of in the procedure by which the physician grants his permission for the implementation of the formulary system. In other words, he subscribes to the by-laws of the medical staff which in fact state that where more than one trade name exists for the same basic drug or its preparation, the basic drug and/or its preparation will be supplied, but not necessarily in the trade name mentioned in the prescription. In doing this he accepts the principle that the pharmacist has used his judgment and selected these drugs which will do the task for him. He has already given me authority to exercise my judgment.

However, if he did come down and insist, I am sure it would be provided for him."

(Hearing, pp. 2227-28)

"MR. HUME: Interchanging which you indicated on your formulary list, would relate I presume to dosage, single medication, single product, single chemical?

PROF. SUMMERS: Either single chemicals or preparations containing identical chemicals combined in the identical type of dosage form.

MR. HUME: Supposing the inactive ingredient was different in one case; a water soluble compound, and in another a petroleum base compound, would you interchange in a case like that?

PROF. SUMMERS: Certainly not, because here the other thing would be different. I specified the dosage form would have to be identical and in the case which you have illustrated, the dosage form would not be identical.

MR. HUME: You, as a pharmacist in the hospital, if a prescription came in for, say, a trade name that had a water soluble base, you would not substitute that for something else on your formulary if you had the same pharmaceutical product but with another inactive ingredient?

PROF. SUMMERS: No. This makes a different preparation altogether."

(Hearing, p. 2266)

"MR. MacLEOD: I think you said something in answer to a question of the Chairman in connection with the use of the products listed in the formulary and the use of products outside the formulary. You said that doctors within the hospital were required in circumstances you outlined to use the products listed in the formulary, is that correct?

PROF. SUMMERS: Not entirely, in this regard, the formulary is not an exclusive list of the only drugs available in the hospital. We carry a much wider selection of drugs than those listed in the formulary.

MR. MacLEOD: You mentioned something about bringing evidence to the Committee, if you have a product or something like that. What was that in connection with?

PROF. SUMMERS: Let us take an example. If we happen to be using Lederle's brand of tetracycline hydrochloride which normally is Achromycin in the hospital, and one of the physicians says, 'I want Steclin -' which is Squibb's brand of tetracycline hydrochloride - 'brought into the hospital for my specific use' - he would be required to have evidence that Squibb's brand of tetracycline hydrochloride produces superior clinical response and/or less side-effects than Lederle's brand of tetracycline hydrochloride.

MR. MacLEOD: I think you said that this had not given you much difficulty.

PROF. SUMMERS: It has never given me any difficulty, in that we have had no one insist on one specific brand. Again I must qualify this because it is quite a complex field.

On the other hand let us take the drug Thyroid which is manufactured by many companies. Our Committee has said that you will purchase, or it has been found through clinical observation that Thyroid purchased from say one or two firms appears to produce a consistent response, whereas some of the others may not, and therefore they say, 'You will buy either from manufacturer 1, 2 or 3, but as long as you confine your purchase to those groups, this is all right'.

MR. MacLEOD: Does that mean in this instance that your hospital would stock 1, 2 and 3?

PROF. SUMMERS: No. 1, 2 or 3."

(Hearing, pp. 2287-88)

3. Purposes and Functions of the Formulary System

The Pharmacopoeia of the Ottawa Civic Hospital describes as follows the purpose and function of the Pharmacy Committee:

- "a. To serve as an advisory group to the hospital medical staff and the hospital pharmacist on matters pertaining to the choice of drugs.

- b. To add to and to delete from the list of drugs accepted for use in the hospital.
- c. To prevent unnecessary duplication in the stock of the same basic drug and its preparation.
- d. To make recommendations concerning drugs to be stocked on the nursing unit floors and by other services.
- e. To evaluate clinical data concerning new drugs or preparations requested for use in the hospital.
- f. To develop a formulary or drug list of accepted drugs for use in the hospital."⁽¹⁾

According to the submission of the Canadian Society of Hospital Pharmacists, "better controlled inventories result through the use of the Formulary System", but "its primary purpose is the promotion of better patient care, through proper drug therapy by the regular review and evaluation of drugs and all policies pertaining to their administration." (p. 8; Hearing, p. 2220). At the Ottawa Civic Hospital, this regular review and evaluation of drugs is made in "Newsletter" issued to the members of the medical staff. About this publication, Dr. Nathan Schechter gave the following information:

"MR. MacLEOD: Does the medical staff need advice on the choice of drugs?

DR. SCHECTER: Yes, we are often asked questions about new drugs and whether they should be stocked in the hospital, and we have been sending around what we call a Newsletter in the hospital with lists of drugs. . . .

. . .

DR. SCHECTER: . . . we issue the Newsletter with some newer drugs coming out with toxic reactions particularly, cautioning the doctors about them.

. . .

(1) Pharmacopoeia of the Ottawa Civic Hospital, Ottawa, 1959.

DR. SCHECTER: . . . So if a drug company is introducing something new, if it is mainly for use by the surgical staff, I discuss the question with the staff of surgeons and their knowledge of it and also with the pediatric division.

MR. MacLEOD: Yes.

DR. SCHECTER: We try to find out as much as we can about the drug before its introduction.

MR. MacLEOD: Do you find that is of assistance to the staff to make that study and make that information available to doctors?

DR. SCHECTER: Yes. We have had favourable comments about it thus far."

(Hearing, pp. 256-59)

In the following evidence, Professor J. L. Summers describes one of the chief functions of a formulary as being an educational tool:

"MR. MacLEOD: . . . Is the principal reason for using a formulary the proliferation of the names, of trade names?

PROF. SUMMERS: Largely, yes. Not only proliferation of trade names, but of actual drugs bearing the name.

There is another very good reason for using a formulary. A formulary is an educational tool, and one of the chief functions of a formulary is to guide the physician by telling him what drugs are available under specific therapeutic categories. Thus if a physician wishes to use a hypnotic, he merely looks in the formulary and there listed under the hypnotics are a selection of drugs which may be used for that purpose.

He then knows there are four or five drugs available, and what they are, and it gives him an opportunity to select one of those therapeutic agents from a list. This is the major purpose of a formulary."

(Hearing, pp. 2267-68)

While its primary function may be educational, the Formulary System, as pointed out above, serves also to obviate the ordering, stocking and listing of a multiplicity of brands of the same drug with the attendant bookkeeping. In this respect, the following evidence was given by Dr. Nathan Schechter:

"MR. MacLEOD: Do you find it desirable to limit the number of drugs that should be used in the hospital?

DR. SCHECTER: Yes.

MR. MacLEOD: For what reason, doctor?

DR. SCHECTER: Well, there are somewhere in the neighbourhood of 67 tranquilizers and 35 antihistamines and many different types of antibiotics. A lot of them are duplication; there isn't space to keep all these drugs.

We try to limit to some extent the number of drugs that are in the hospital now."

(Hearing, pp. 257-58)

"MR. BUCHANAN: One other question, on this Pharmacy Committee that you have, you mentioned one of their duties was the limiting of the number of drugs, getting together to decide what drugs and how many. I am wondering how you decide, is it on the basis of, perhaps, price or a combination of price say and the reliability of the company?

DR. SCHECTER: Well, I would say first of all reliability of the company, and price is a second consideration. Hospitals are in a different position, as you know, because they buy their drugs cheaper, no sales tax, 40 per cent or more off. We are more concerned with the quality of the drug and also whether it is going to reduplicate what we already have or whether - if it is a very expensive drug then the price structure comes in, and that is when we discuss the drug with the surgeons or pediatricians or obstetricians as to whether they think it is of value to stock it. . . ."

(Hearing, pp. 269-70)

4. The Quality of Drugs Dispensed under the
Formulary System

It appears that in a controlled community such as a hospital the members of the medical staff are confident that only drugs of good quality will be dispensed to the patients by the resident pharmacist. In this respect, the following evidence was given by:

(1) Dr. J.P. Gemmell, Associate Professor of Medicine at the University of Manitoba:

" . . . If I am dealing in the hospital and I am Chairman of the Committee of Pharmacy and Therapeutics at the Winnipeg General Hospital, this is done in practice to a certain extent, and we are trying to make it official as to enable the pharmacist to substitute chemically identical things. In other words, if you write a trade name or a generic name, the pharmacist will use one particular material.

This means then that the pharmacy, and to a certain extent our Committee have taken the responsibility of trying to go through the various - I mean there may be twenty identical drugs offered by twenty different firms - to try to pick out something between the most expensive one with a trade name promoted, and the cheapest one on which we may have no assurance that this is really manufactured under proper circumstances. I would say again, this question of control of quality of drugs is a field where Dr. Nickerson is much more qualified than I am. Therefore, in a controlled field such as a hospital, I am in favour of allowing generic name drugs to be supplied or substituted. . . ."

(Hearing, p. 526)

(2) Dr. Nathan Schechter, medical practitioner in the City of Ottawa and Chairman of the Pharmacy Committee of the Ottawa Civic Hospital:

"MR. MacLEOD: You order drugs or prescribe drugs by the generic names in the hospital. They would normally be filled from the hospital pharmacy.

DR. SCHECTER: Yes.

MR. MacLEOD: So you have in that case a safeguard.

DR. SCHECTER: Yes.

MR. MacLEOD: You would assume that the purchases for the hospital are all of satisfactory quality.

DR. SCHECTER: That is right."

(Hearing, p. 261)

(3) Dr. C.C. Misener, medical administrative assistant to the Director General of Treatment Services, Department of Veterans Affairs:

"MR. MacLEOD: Now, has the policy of the Department in ordering in generic names posed any problem as to the quality of the drugs which you have obtained? Perhaps I should say, resulted in any difficulties in relation to quality?

DR. MISENER: Naturally our doctors want to be assured that the drugs are [of] proper quality before giving them to the patients. It is the policy to have newer drugs obtained from less known companies assayed or tested by the Food and Drug Division of the Department of National Health and Welfare. It is time consuming. Mr. Shaw can tell you more about this. Sometimes shipments have to be rejected due to low quality so it poses that problem, at least.

MR. MacLEOD: Yes, you do follow the practice of testing drugs which are purchased?

DR. MISENER: The least well known companies I think I would say."

(Hearing, pp. 336-37)

"THE CHAIRMAN: Would it be true that the great majority of drugs that are purchased by or under the Chief of Service (Medicine) are purchased by generic name?

DR. MISENER: Yes.

THE CHAIRMAN: That is a fact?

DR. MISENER: That is a fact."

(Hearing, p. 344)

5. Degree of Co-operation Given by the Physicians
to the Formulary System

With respect to the co-operation obtained from the members of hospitals' medical staffs and their appreciation of the Formulary System, the following evidence was given to the Commission:

(1) by Dr. C.C. Misener:

"MR. MacLEOD: Do you feel that your policy has the approval of the best medical men in Canada?

DR. MISENER: We employ some of the very best, and that is their opinion, that is true.

THE CHAIRMAN: You have indicated that it is the policy of your Department to purchase drugs by generic name, and then you referred to this booklet, the list of approved drugs. Are they all in generic name?

DR. MISENER: In so far as possible they are listed by generic name.

. . .

MR. FRAWLEY: I take it that that requires the, shall I say, the co-operation, of the prescribing physicians that are employed in your Department?

DR. MISENER: Yes.

MR. FRAWLEY: Because each prescription must be given by a physician?

DR. MISENER: That is quite true.

MR. FRAWLEY: And he would have to be convinced that that was a suitable way to prescribe the drugs, by their generic name?

DR. MISENER: Yes.

MR. FRAWLEY: And you have had no difficulty, I take it, in any way in that respect?

DR. MISENER: With three or four exceptions. I didn't mention that a Chief of Service (Medicine) can obtain on requisition one particular trade name of a drug if he says

that that is the only make of drug which will satisfy his treatment requirements, but I can only recall offhand in the last three or four years, three or four examples of where he insisted on so buying a certain trade name. I think that answers your question. They must find the generic drug satisfactory otherwise.

. . .

THE CHAIRMAN: Just to be clear on that, do you find that most of the physicians who are practising in the D.V.A. hospitals agree with the policy of purchasing by generic name, or do they just accept it?

DR. MISENER: I cannot answer that. The only dealings we have in this connection are with the Chiefs of Service (Medicine). I should think their staff in general would agree with their Chief."

(Hearing, pp. 339-44)

(2) by Professor J.L. Summers:

"THE CHAIRMAN: Are doctors practising in the hospital that have adopted the formulary system entitled to refuse to accept the formulary system?

PROF. SUMMERS: They are, but in that case the Hospital Board would refuse the right to have them on the staff of the hospital.

THE CHAIRMAN: They are not on the staff of the hospital then?

PROF. SUMMERS: That is right, sir, yes. I think we must realize, sir, in the hospital community this is a very carefully controlled community. It is a very close community, and in all of my years in hospital pharmacy we have never had such an instance as this occur where our judgment has been questioned.

THE CHAIRMAN: What we are getting at of course is how it works because we have had a good deal of evidence to the effect that a doctor must be in a position to select the particular drug, that is, the specific trade name drug that he desires which he feels is better for a particular patient. In private practice that seems to be put forward. You haven't had too much trouble with that in hospitals?

PROF. SUMMERS: No, we haven't, sir. We have had no problem."

(Hearing, pp. 2228-29)

6. Extent of Use of the Formulary System

According to the brief presented by the Canadian Society of Hospital Pharmacists (p. 61), the Formulary System is "an accepted part of modern hospital practice" (Hearing, p. 2216). This statement is in conformity with the views expressed to the Commission by the following witnesses:

(1) Dr. C.C. Misener, medical administrative assistant to the Director General of Treatment Services at the head office of D.V.A. and Secretary of the Departmental Pharmaceutical Committee:

"DR. MISENER: . . . They [the Chiefs of Service (Medicine) in D.V.A. Hospitals across Canada] consider it is good medicine to encourage the prescribing of drugs and requisitioning by generic name.

They feel a most useful adjunct towards encouraging that idea to have an approved list of drugs for use in D.V.A. hospitals.

This is the book that I have here. The staff then and the interns and residents are actively encouraged to prescribe from this book.

THE CHAIRMAN: What is the title of that book, Doctor, just so we will have it on the record?

DR. MISENER: 'Approved List of Drugs for use in D.V.A. Hospitals'."

(Hearing, pp. 330-31)

(2) Dr. J.D. Ross, Minister of Health, the Province of Alberta:

"I may say, sir, that this practice is being carried with the approval of the medical staffs of many of the hospitals in Alberta today to the benefit of the economy of the provision of drugs under our programmes."

(Hearing, p. 866)

(3) Mr. J.L. Summers, Associate Professor of Pharmacy at the University of Saskatchewan and Director of Pharmaceutical Services:

"MR. FRAWLEY: How extensive is the use of the formulary system in Canadian hospitals?

PROF. SUMMERS: I have no precise knowledge of this, sir. I would say reasonably extensive, particularly among the larger hospitals which employ pharmacists.

For your information this is also an increasing practice in many of the small hospitals in Saskatchewan where we use the Regional Hospital Council system, and have a regional hospital pharmacy. We have found it is quite possible to put this system into practice in many of our smaller hospitals who have medical staffs as small as two or three members.

. . .

MR. FRAWLEY: . . . I just wondered how general the formulary system was. I did understand that in a general way it was almost universally practised now in large hospitals such as your University Hospital in Saskatoon and ours in Edmonton, Alberta.

PROF. SUMMERS: I would say it was universally used in the progressive hospitals."

(Hearing, pp. 2233-35)

It is interesting to note that the use of the Formulary System is recommended by the Canadian Council on Hospital Accreditation. As stated by its Executive Director, Dr. W.I. Taylor:

" . . . while the six essentials for a pharmacy as stated in the Standards [Standards for Accreditation of Canadian Hospitals], do not mention either a pharmacy and therapeutics committee or a formulary or drug list, both are considered desirable because of their potential contribution to better patient care in hospitals, and hospitals of all sizes and types can put the principles into effect modifying the function to suit the institution".⁽¹⁾

(1) Dr. W.I. Taylor, "Pharmacy and Therapeutics Committee and the Formulary System", The Hospital Pharmacist, Vol. 12, No. 3, May-June, 1959, p. 117.

7. The Formulary System as an Economizing
Device for Hospitals

By decreasing the duplication of products on the shelves, the Formulary System makes it possible for hospitals to buy in larger quantities. This, combined with the elimination of brand name protection and buying by tender, enables the hospitals to reduce their drug costs substantially. This factor is stressed as follows in the submission of The Canadian Pharmaceutical Association, Inc.:

"This system works to effect reduced costs to the hospital. From the manufacturer's point of view, the formulary system tends to substantially reduce, in hospitals and government institutions, or, indeed, eliminate the normal protection afforded his brand name. With sales made to hospitals under the tender system and the elimination of brand name protection, the manufacturer is forced into an extreme competitive field, price-wise, if he wishes to benefit by a coincident prestige and promotional value of having his particular brand available to physicians in the hospital. . . ."

(Association brief, p. 50;
Hearing, pp. 2421-22)

CHAPTER XXVI

CONCLUSIONS AND RECOMMENDATIONS

This inquiry has been concerned with many aspects of the manufacture, distribution and sale of drugs. The Green Book, which is reproduced in extenso as Appendix Q to this report, constitutes a summary of the information received by the Director of Investigation and Research in the inquiry. Similarly the preceding chapters contain a summary of the material put before the Commission. Therefore this concluding chapter will deal only with those matters on which the Commission makes suggestions or recommendations.

1. The Prescribing Physician and the Cost of Medication

The prescribing physician's first aim should be to select the most suitable drugs for the treatment of his patients. Only when two or more drugs are approximately equal in their treatment value, or when the physician has a genuine doubt as to which drug will be most effective, should economic considerations be taken into account.

From the evidence as a whole it appears that physicians could prescribe more economically and with the same efficiency over a substantial part of their practice if they knew more about the cost of the various drugs. It is also evident that they cannot be expected to conduct extensive research into drug costs in view of the exacting nature of their work, the multiplicity of drugs in current use and the great number of new drugs poured into the market every year. The medical schools, the professional associations and possibly the federal or provincial Health Departments may however give them some assistance in obtaining cost information.

As pointed out in the Final Report of the Hinchliffe Committee (see section 4 of Chapter XXIV of the present report), medical

schools could make their students more aware of economy in prescribing if medical training emphasized the importance of minimizing patients' expenditures on drugs. Practising physicians would be assisted also if medical schools' refresher courses provided information on the cost of medication.

The Commission considers that the Canadian Medical Association and its provincial branches, because of their independence and the resources upon which they can draw, are in an excellent position to provide the relevant cost information to their members. Our attention has been drawn to the series of informative articles prepared by the Pharmacy Committee of the British Columbia Division of the Canadian Medical Association (see section 2 of Chapter XXIV). It is desirable that similar articles be published regularly and frequently, cover a wide field, and reach every physician practising in Canada. If the medical associations do not follow this course, then the federal or provincial Health Departments could consider the advisability of publishing a circular similar to the Prescribers' Notes formerly issued by the British Ministry of Health (see section 2 of Chapter XXIV) and of distributing copies of it to final year medical students as well as to practising physicians.

Unless physicians are fully informed on the cost of alternative products, it is not likely that there will be an opportunity for competition to reduce drug prices to patients, for the latter are dependent upon the selection made by the doctor.

2. Adaptation of the Formulary System to the Retail Drug Trade

The wide use of brand names plays an important part in modifying competition between similar drugs manufactured by different drug firms. This is a form of product differentiation which is of much greater significance in the distribution of drugs than in the distribution of products which the consumer can choose for himself. The role of brandnames in the distribution of drugs is described in the Green Book (p.219, para.384):

"Wide use is made of trade names in the drug field. Primarily, these serve the same purpose as in any other field, that is, a trade name identifies a product of a particular firm. However, trade names are used in a somewhat different way than in most other fields. Instead of using one trade or brand name for its line of products, a drug firm usually uses a trade name for each particular drug which it sells. The main purpose of using a trade name is to have the trade name displace the chemical or

generic name. To the extent that this is accomplished, the trade-named product is specified when the drug is required as, for example, when a doctor prescribes the drug. . . ."

The consequence outlined above is avoided in hospitals where the formulary system operates. There drugs are prescribed and dispensed by generic names. This practice eliminates unnecessary duplication in stocks of drugs, for only selected drugs, rather than a wide range of brands, are purchased. The key to the system's success appears to be the professional hospital pharmacist and the hospital's medical committee on pharmacy and therapeutics. The evidence contained in Chapter XXV shows that the adoption of the formulary system has occasioned very little difficulty between the hospital pharmacy and members of the medical staff. Nearly all large hospitals and in some provinces many of the smaller ones have adopted the formulary system. The medical staffs of these hospitals, which include most of the ablest and most highly qualified practitioners in Canada, have apparently been well satisfied to carry on under a system which tends to reduce the number of pharmaceutical preparations available for dispensing.

While there was no unanimity on this point, many persons and organizations expressed the opinion that the widespread use of brand names was an important factor in the high cost of medication by preventing the dispensing of lower priced generic preparations. Some proposed as a remedy that the formulary system now widely used in hospitals should be applied broadly in the retail drug trade. A change in provincial legislation along the lines of the amendment made in April, 1962 to The Alberta Pharmaceutical Association Act (see section 4 of Chapter XXIII) would give an opportunity for such a development. Such legislation would enable pharmacists to substitute a pharmaceutical equivalent to a brand-named preparation specified in a prescription.

Those who advocated wider opportunities for the dispensing of drugs by generic name clearly indicated that they were not suggesting any interference with the freedom of the physician to designate the preparation to be dispensed. This freedom is maintained under the amendment to the legislation in Alberta referred to above. It may, however, be argued that any legislation along these lines might well prove to be useless. Indeed it would be without effect if all physicians, when prescribing, were to use pads with the words "no substitution" printed on them or were to designate a manufacturer's name in each case. For this reason the effectiveness of such a measure would depend upon the behaviour of physicians. According to the study made by Dean Hughes and Professor Walker, 28 per cent of all prescriptions are for brand-named preparations for which at least one generic equivalent exists.

According to the surveys made by Mr. J. Frank Holland, this percentage was 37.2 for 1960 and 47.8 for 1962. In contrast to these figures, not more than 14.2 per cent of all prescriptions were written with non-proprietary terminology.

The physician's preference for prescribing by brand names for patients outside hospitals is largely accounted for by the following factors:

(a) Preference for a Particular Preparation on Therapeutic Grounds

For therapeutic reasons, medical practitioners may prefer one preparation to all others. As shown in section 3 of Chapter X, various preparations of the same drug are not necessarily therapeutic equivalents, even if administered by the same route or in similar dosage forms. Their efficacy may not be the same. The possible side effects may be different. Independently of the respective merits of the various preparations, a particular patient may definitely react to one in a better way than to the other simply because of his own idiosyncratic behaviour. For any of these reasons, physicians may prefer one make to all others.

(b) Repeated Selection of the same Preparation for Reasons of Convenience

Even if initially they have no preference between various makes of a given drug, physicians may feel it desirable to prescribe the same make on a series of occasions. For instance, if over a period of time the same preparation has been dispensed to all their patients, side effects, if any, may be linked easily to that preparation. Moreover, a doctor's loyalty to a particular make may be explained by his knowledge of its mode of action derived from past experience and by a consequent reluctance to use another preparation which may be just as good or even slightly better, but whose mode of action the prescriber does not know. This kind of loyalty has been particularly well described by Mr. R.B. Thompson, of Cyanamid of Canada Limited, in an excerpt from his evidence quoted in section 8 of Chapter VI.

It is essential to maintain the physician's freedom to designate not only the drug, but also, if he feels it necessary, the particular pharmaceutical preparation to be dispensed to his patient under conditions described above in (a) and (b). That these circumstances are rather exceptional, however, seems obvious from the evidence on the experience of hospitals which use the formulary system. Dr. C.C. Misener, Medical Administrative Assistant to the Director General of Treatment Services, Department of Veterans Affairs, could recall offhand only three or four examples over a period of three or four years in which a Chief of Service (Medicine) had insisted on dispensing

a particular preparation of a given drug (see section 5 of Chapter XXV). Again Professor Summers, Director of Pharmaceutical Services at the University Hospital in Saskatoon, stated that no member of the medical staff had ever insisted on one specific brand (see sections 2 and 5 of Chapter XXV). The Commission is of the opinion, therefore, that the low proportion of non-proprietary prescriptions is mainly accounted for not by factors (a) and (b), but by the other factors described below.

(c) Inferior Quality of Some Preparations

Some physicians resort to brand names in prescribing to avoid any possibility that inferior drugs may be dispensed to their patients. ⁽¹⁾ To some extent this indicates that physicians have less confidence in the retail pharmacists than in the hospital pharmacists, for otherwise physicians would be willing to rely to the same extent as they do in hospitals on pharmacists' judgment in the selection of the actual drug to fill a prescription. However, confidence in the hospital pharmacist may be more readily given because the selection of the drugs which are listed in the formulary is supervised by the committee of physicians. Such a situation does not prevail when the individual druggist makes his own selection. From the evidence reproduced in section 7 of Chapter XXIII, it appears however that the proportion of non-proprietary prescriptions might be substantially increased, if as a result of more extensive inspections and assays by the Food and Drug Directorate all drugs offered on the Canadian market could, without substantial risk, be presumed to be of good quality.

(d) Physicians' Habits

To a substantial extent, habits determine whether proper or brand names are used in prescribing. Even medical practitioners seem vulnerable to the magic of a brand name well publicized. No other explanation is possible for a phenomenon described in evidence quoted in section 2 of Chapter II, according to which the choice of terminology largely depends on the relative frequency with which various drugs have been designated under their non-proprietary names or under brand names in the literature of the period shortly after their development

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- (1) For this reason, the Alberta Division of the Canadian Medical Association adopted recently a resolution recommending that its members make extensive use of the "no substitution" clause, according to a letter dated January 14, 1963, addressed to the Commission by its secretary-treasurer, Dr. Wm. Bramley-Moore.

Professor Summers cited the examples of cortisone, bacitracin and neomycin which first became known under their proper names and for which even nowadays there are very few brand name prescriptions. This phenomenon emphasizes the importance, also stressed by Mr. Grant L. Kalbfleisch, Secretary of the Canadian Drug Advisory Committee, of devising a non-proprietary name as soon as the drug is made known to the medical profession.

In order to appreciate the impact of the proposed measure, it is also necessary to consider the behaviour of pharmacists. Indeed, the measure would be totally ineffective if, in spite of legislation which would enable them to do so, pharmacists avoided substituting a pharmaceutical equivalent for a brand-named preparation specified in a prescription because of fear of increasing their legal responsibility or for any other reason. To be effective, the legislation should be drafted in such a way that, whenever a substitution is permissible, the choice of the preparation would be the responsibility of the pharmacist. It would also be necessary to define the term "pharmaceutical equivalent" with great precision, a task not easily achievable, in view of the evidence summarized in section 3 of Chapter X. Moreover, even if these conditions were fulfilled, the measure would still be ineffectual in its aim of reducing prices if and to the extent to which pharmacists were reluctant to dispense the products of little known or unknown generic manufacturers, as long as the latter remained the principal competitors in terms of price.

To sum up, provincial legislation along the lines of the amendment made in April, 1962 to The Alberta Pharmaceutical Association Act might bring about a reduction in the prices of some prescription drugs for which there are generic equivalents. Furthermore it might enable retail pharmacists to carry a much smaller total volume of prescription drugs in stock and thus to effect some saving in overhead. It is the opinion of the Commission, however, that while opportunity for the dispensing of drugs by pharmacists along the lines of the formulary system would be a desirable course, its effect would be limited unless there were other developments leading to wider prescribing of drugs by generic name. To be effective, the measure would require the co-operation of physicians and pharmacists. Last, but not least, governmental inspection and testing services would have to be placed on a level adequate to ensure that all prescription drugs offered for sale in Canada are safe to use and of good quality.

3. Control Measures Designed to Enhance the Quality of Drugs Marketed in Canada

Dr. C.A. Morrell, Director of the Food and Drug Directorate, stated that the staff of this governmental agency would need to be increased to two or three times its present strength to be able to test and check drugs adequately in Canada (see section 1 of Chapter VIII).

Moreover, the evidence before the Commission shows that, as a rule, physicians will avoid prescribing, and pharmacists will avoid dispensing low-priced preparations of little known or unknown manufacturers without reasonable assurance as to the quality of the product. For this reason, inadequate inspection leaves psychological barriers to competition, and thus operates indirectly to restrict freedom of trade and limit the impact of competing products on the market. In order to provide greater opportunity for competing products of merit, the Commission recommends more stringent regulations with respect to the manufacture, promotion and introduction of drugs and also a considerable enlargement of the staff of the Food and Drug Directorate in order to ensure a thorough enforcement of the regulations.

In the opinion of the Commission, the following changes should be made in the regulations:

(a) As appears from the evidence of Dr. C.A. Morrell (see section 1 of Chapter VIII), some foreign firms, as a measure of courtesy, allow the inspectors of the Food and Drug Directorate to visit their plants, but only with respect to Schedules C and D drugs has the Directorate the authority to inspect "the premises in which drugs are manufactured and the process and conditions of manufacture therein".⁽¹⁾ That testing is no substitute for inspection was asserted by Professor J.L. Summers:

"PROF. SUMMERS: . . . It is the responsibility of Government to set such standards as it deems are adequate to protect the people of this country and to see that the manufacturer observes his obligations and responsibilities. Now, this can be done by inspecting these plants. No knowledgeable person in the field of pharmacy could walk into a plant and spend a day with them and not learn more and know more about the quality of the product which they produce than analytically, by testing they could learn in five years. It is the products that are produced. . .

MR. FRAWLEY: Let us be very . . .

PROF. SUMMERS: You can't inspect quality into the product. It must be built in by knowledge and ability."

(Hearing, p.2254)

(1)

Appendix B to this Report, Food and Drugs Act, s.12.

In view of these considerations, the Commission recommends that section 12 of the Food and Drugs Act be made applicable to all drugs.

(b) Under the Food and Drug Regulations, (1) "no person shall sell a new drug, unless the manufacturer thereof has filed . . . a new drug submission . . . that includes . . . detailed reports of the tests made to establish the safety of the drug" In the opinion of the Commission, such reports should establish not only the safety, but also the therapeutic effectiveness of the drug. This reform would make mandatory a joint evaluation of toxicity and efficacy such as was advocated by Professor Mark Nickerson in the excerpt from his evidence quoted in section 3 of Chapter VIII. Whenever, in the judgment of the Directorate, the safety and the efficacy of the drug have not been established with respect to a drug "new" on account of its composition, the name of such a drug should be added to Schedule H, (2) after due notice has been sent to the applicant and opportunity to be heard given to him. Schedule H has just been added to the Food and Drugs Act in the course of the current session of Parliament and consists of drugs which nobody is allowed to sell or distribute.

(c) The Food and Drug Directorate should be given the duty of inspecting and assaying samples from a sufficiently large number of batches of every prescription drug manufactured in Canada or imported from abroad to make it reasonably certain that it meets minimum standards of purity and therapeutic efficacy. Such matters as the base used and the ingredients intended to slow down or speed up the absorption of the drug should be investigated. Indeed the Commission does not recommend that such assaying be done on a sample from every batch of every prescription drug only because of fear of placing too great a burden on even an expanded Food and Drug Directorate.

In his evidence before the Commission (see section 5 of Chapter VIII), Professor Mark Nickerson stated that the Canadian Drug Advisory Committee, of which he is a member, had participated in drafting a new set of regulations, the adoption and enforcement of which would give reasonable assurance that all drugs marketed in Canada are of good quality. Any measure intended to fulfil this aim should, in the opinion of the Commission, receive close attention from the Government. The legal responsibility for assuring the safety and effectiveness of any drug should, however, remain the responsibility of its manufacturer or distributor. The role of the Directorate is, and should be, to see that

(1)

Appendix C to this Report, Food and Drug Regulations, C.01.302.

(2)

Appendix B to this Report, Food and Drugs Act, s.14A.

the responsibilities of all are fulfilled.

4. Recommendations with Respect to Brand Names

The Commission considered if and to what extent brand names are valuable from a social point of view. Information reproduced in sections 2 and 4 of Chapter II shows that brand names fulfil a useful function with respect to pharmaceutical compounds. According to Dr. G. Stecher and Dr. Lloyd C. Miller, except in the case of some natural aggregates of substances such as extracts of plant or animal origin, each active ingredient has its own proper name, but there is no non-proprietary name for the mixture itself. In such circumstances, a drug combination, as pointed out by Professor Summers, is much more easily described by a single brand name than by the list of all its active ingredients. At the same time the prescribing physician has to keep in mind the ingredients which make up the compound. It should be remembered that mixtures of drugs account for about 59 per cent of the 7776 drugs described in the Compendium of Pharmaceutical Specialties, 1960 (see Table 30) and for 42 per cent of all prescriptions according to the survey conducted by Dean F.N. Hughes and Professor G.C. Walker (see Table 32).

Brand names applied to single drugs and the few official compounds that exist may be of considerable commercial value, but, from a medical and social point of view, they are of very doubtful value and may actually have detrimental aspects. The Commission can draw no other conclusion from the four following propositions which the evidence clearly establishes:

(a) There is no real virtue inherent in mere names and, to use the words of Dr. C.A. Morrell, ". . . the significant thing is the facilities, ability and attitude of the manufacturer. . ." (Hearing, p.135).

(b) No conscientious physician will prescribe a drug without knowing its proper name and the family to which it belongs.

(c) All names may lead to confusion, but while a generic name, when properly coined, is informative, a brand name, as a rule, does not indicate the nature of the drug and the class to which it belongs.

(d) While brand names vary from firm to firm and, to a great extent, from country to country, non-proprietary names tend to be the same all over the world, and for this reason cannot be dispensed with.

There is a consensus of opinion on these four points. This being so, what value have brand names? Some contend that they are less

cumbersome and for this reason often easier to remember than proper names. But this is of no real value if the prescribing doctor must remember also the more difficult non-proprietary name, the manufacturer and his reputation. In short, easy as it may be to remember, the brand name is always one more name to remember.

Moreover the following inconveniences result from the use of brand names. Firstly, they increase needlessly the multiplicity of names and thereby the risk of confusion (see section 8 of Chapter XXIII). Secondly, as most brand-named products are promoted individually, they tend to increase the expenditures on advertising and promotion. Thirdly, to the extent that their use is the result, not of a rational choice, but of mere habit, they tend to displace proper names and thus have the effect of reducing competition by preventing the dispensing of other preparations of the same drug. That this effect is not negligible is evident from the attitude of the drug manufacturers, who emphasize the usefulness of brand names in helping them to keep the goodwill built up by the excellence of their products. But the manufacturer's name is sufficient for this purpose and if brand names have added effect, it is only to the extent that physicians prescribe, not from rational choice, but from mere habit. For whenever he now prescribes a brand-named preparation of a given drug, because he prefers it to all others for therapeutic reasons, or knows its mode of action better, or wishes to administer the same preparation on a series of occasions, or fears the possibility of an inferior drug being dispensed to his patients, in all such circumstances a conscientious physician would, if there were no brand names, specify on his written prescription the manufacturer's name in addition to the proper name of the drug.

The Commission believes that significant relief from the foregoing disadvantages, associated with the intensive as well as extensive use of brand names, may be obtained by making wider use of and laying greater emphasis upon generic names. It is therefore recommended that labels, advertisements and other descriptive material relating to single ethical drugs and official compounds be required to carry the proper name of the drug prominently and in type at least as large as that used for the brand name. It is also recommended that a study be made to ascertain if and to what extent a similar requirement would be feasible in respect of compound ethical drugs.

5. Conclusions on Retail Pricing Practices

The retail pharmacist is both a practising professional man and a business man engaged in trade. In this respect his position is unique and there is always a danger that his two functions may become confused, or rather that the dividing line between the two may

become blurred.

The matter of the professional fee charged by a druggist for professional services is outside the scope of the Combines Investigation Act. Nevertheless the exercise of the professional function is so closely linked with the distribution of a commodity that there is great difficulty in keeping the two aspects from intermingling. This is apparent in some of the prescription pricing schedules which have been prepared or recommended by associations of pharmacists. While professional services are not included under the Combines Investigation Act, there might be objection if uniform professional fees were established for the purpose of ensuring that the final drug prices charged to customers would be uniform. Any such design would involve confusing the druggist's professional function with his other function as a retailer of goods, and agreements, arrangements or understandings to charge uniform prices for goods do fall within the purview of the Combines Investigation Act.

We have seen that almost invariably retail druggists set their drug prices in relation to the manufacturer's list prices. For prepared drugs, both prescription and proprietary, the retailer's selling price is often the list price, plus the professional fee, if any, in the case of prescriptions. The sample of prescription prices taken by The Saskatchewan Pharmaceutical Association (see section 4 of Chapter XXI) indicates that where variations in price do occur they are likely to be quite small. For prescription drugs compounded by the pharmacist the total price charged the customer is subject to greater variation. This greater price variation appears to be due not to departure from the manufacturer's list price, but to variations in the amount added thereto by the pharmacist for his professional fee.

The evidence before the Commission does not indicate that the high degree of uniformity in retail drug prices is due to any agreement or arrangement between druggists or to any rules of professional conduct adopted by pharmaceutical associations. It appears to be due chiefly to a general feeling among pharmacists that price cutting lowers the dignity of the profession. Rules of professional conduct like those quoted in section 2 of Chapter XXI clearly indicate this attitude. It is possible for such rules to be interpreted as placing pharmacists under some moral pressure not to cut prices at all, but the Commission has seen no proof that this is so. There is evidence that complaints of price cutting by one druggist have been received by pharmaceutical associations from one or more other druggists, but we have no evidence that the associations have ever done anything about these complaints.

The practice of coding prescriptions, however, comes perilously close to price fixing by agreement. The coding of a prescription means that the pharmacist places on a prescription or a copy thereof a code symbol which will indicate to any other pharmacist

who sees it the price charged or quoted by the first pharmacist. The rules of some provincial pharmaceutical associations state that all prescriptions or copies given back to a customer, for which the pharmacist has charged or quoted a price, should be coded. In some cases the rule says they must be coded. In our opinion the practice of coding prescriptions should be abandoned. There seems to be only one prime reason for the practice, viz., that any other pharmacist to whom the prescription is taken will identify the code symbol and quote or charge the same price.

6. Measures Intended to Reduce and Control Expenditures on Advertising and Promotion

Various proposals were suggested to the Commission to reduce the huge amounts of money spent on advertising and promotion by drug manufacturers. Advertising expenditures, as such, would not appear to come within the Commission's terms of reference but in view of the importance which was attached to this feature of drug promotion the Commission considers it appropriate to make some comment on the proposals which were advanced. In so doing, the Commission has in mind that the necessity to spend large amounts of money on advertising and promotion may serve as a barrier to entry into the drug industry or may restrict the range of products on the part of established manufacturers. In this respect, the experience of Nordic Biochemicals Ltd., described in the brief submitted by that firm, is particularly revealing (see section 1 of Chapter XII). There is also the point that expenditures on advertising and promotion are largely concentrated on branded drugs and are directed to securing an exclusive position for the products featured. It is true that rival drug manufacturers use advertising and promotion as competitive means, but the exclusive nature of the branded drug product tends to lessen the competitive aspect and strengthen the element of monopoly which exists for a product produced by a patented process.

Three methods of reducing the volume of expenditures on advertising and promotion have been recommended to the Commission. The first would consist in so amending the Income Tax Act that a certain percentage of sales would represent the maximum expenditure on advertising and promotion which drug manufacturers could treat as legitimate business expenses for income tax purposes. For two reasons the Commission does not think that this would be an appropriate remedy. Firstly, advertising and promotion is one of the major costs of doing business in other industries than drug manufacturing. Consequently there does not seem to be any justification for discrimination against the drug manufacturing industry in the field of income tax law. Secondly, the adoption of such a proposal would be unjust to the wholly independent Canadian firm. While all firms operating in Canada would be restricted

in their advertising and promotional activities, the Canadian subsidiaries of American firms would reap some benefits from the uncontrolled expenditures made by their parent firms in the United States.

A second proposed method consists in controlling the types of advertising and promotion. More stringent regulation of drug manufacturers' advertising and promotion might result in a limitation of expenditures thereon. Although the basis of federal jurisdiction in this field is Criminal Law and the aim of regulations is the preservation of public health, regulations for this purpose may also tend to result in greater economy in the distribution of drugs.

The curtailment of advertising and promotional activities which are potentially dangerous or harmful from the viewpoint of public health may lead to an over-all reduction in expenditures for such purposes and, perhaps, to more active competition among drug firms in cost-saving rather than in cost increasing ways.

The main channels of communication between manufacturers of ethical drugs on the one hand and physicians, pharmacists and hospitals on the other, are detail men and salesmen, advertising in journals, direct mail and samples. These means are used in varying degrees by different firms to convey useful information. The Commission is satisfied, on the evidence, that very frequently the message does not receive the attention of the recipient, and that in any event it is sometimes incomplete and may be misleading. Detail men are not always as expert as they should be and, even when they are, they do not always provide objective information. There is a danger that drug manufacturers' promotional activities will be self-defeating in that medical practitioners generally may cease to pay any serious attention to the flood of material directed to them. It appears desirable that before this stage is reached (for some it appears to have arrived already) members of the industry should examine their promotional methods critically and select only those which will provide physicians with information which will assist them directly in their practice. There appear good grounds for proposing a critical examination of advertising and promotion in connection with federal health control. The advice and suggestions of the medical associations would be of value and would be helpful in seeking means for improvement.

The Commission found it difficult to understand the fact that the Canadian Pharmaceutical Journal carries many advertisements appealing to the profit motive in view of the desire professed by The Canadian Pharmaceutical Association, Inc. to advance the professional status of pharmacists. The fact that the products advertised were mostly patent medicines does not justify this type of appeal in a professional journal, and indeed, makes it less excusable. It is true that patent medicines may be sold in any kind of establishment like

ordinary goods. But a pharmacist should not be regarded as an ordinary merchant. His role in selling prescription drugs consists in most cases in dispensing the brand-named preparation prescribed by the physician. But in buying a patent medicine in a pharmacy rather than in an ordinary store, a person may expect to receive some professional advice on his choice of drug. Although there is no evidence that pharmacists yield to the profit motive when advising their customers, the fact that drug manufacturers' advertisements attempt to appeal to pharmacists' profit motives does not reflect a high regard for the latter's professional standards. Indeed such advertisements should be frowned on by pharmacists and it is hard to understand their appearance in their Association journal.

To secure some improvement in the present situation with respect to the advertising and promotion of drugs, consideration should be given to the advisability of regulating these activities in a more stringent manner on the following points:

1. The distribution of samples might be more closely controlled. In a portion of its brief, quoted in section 3 of Chapter XIV, The Canadian Pharmaceutical Association, Inc. stressed the dangers arising from the mishandling of the samples distributed by drug manufacturers for purposes of advertising. These dangers would be greatly lessened if not removed by prohibiting the distribution of free samples of any drug other than a patent medicine for purposes of advertising and promotion, except when a physician or a pharmacist makes a separate specific written request for samples of the particular drug or drugs in which he may be interested. As of now, this procedure is mandatory only in the case of narcotics. Moreover, it should be noted that since the adoption of Bill C-3 in the course of the current session of Parliament, "The Governor in Council . . . may make regulations . . . respecting the distribution or the conditions of distribution of samples of any drug. . . ." (1)

2. In the United States, a recent amendment to the Federal Food, Drug, and Cosmetic Act makes it obligatory that all advertisements of prescription drugs include information in brief summary relating to side effects, contraindications, and effectiveness as required in regulations issued under the Act. In Canada, deceptive advertising is forbidden. (2) Would it not be appropriate to go one step further and prohibit the dissemination of information which, while accurate, is incomplete with regard to side effects, contraindications and effectiveness? According to Professor Mark Nickerson, the Committee on Pharmacy of the Canadian Medical Association recommended in 1960 that all advertising should carry an indication of the toxicity of drugs.

3. In view of the safeguards which are necessary in the production and distribution of drugs there would appear to be good grounds

(1)

Appendix B to this Report, Food and Drugs Act, s.24(1)(n).

(2)

Ibid., s.9(1).

for considering the possibility of prohibiting any direct appeal to the profit motive in the advertising and distribution of all drugs. Such appeals are absent, of course, from advertising directed by drug manufacturers to the medical profession and in the interest of public health it may be desirable to eliminate such appeals from all drug advertising.

If, in the interest of public health, the various steps proposed above are justified their adoption and enforcement might have beneficial results in more than one direction. Some health hazards would be eliminated, but the prohibition of advertising and promotional activities deemed harmful or dangerous is likely to entail as a corollary an over-all reduction in the volume of expenditures on advertising and promotion.

The enforcement of the present regulations on advertising to doctors and pharmacists could be an important part of the control measures proposed above. Dr. C.A. Morrell stated that his Directorate had exercised no supervision over such advertising - except for one particular drug - up to the moment at which he testified (see section 4 of Chapter VIII). The following remarks of Dr. Mark Nickerson on this subject have been quoted earlier in this report:

"I think in my own mind that drug advertising to the physician probably should be re-evaluated in total. For a long time in both Canada and the United States there have been quite strict regulations on drug advertisements to the lay public because it was felt that they were not in a position to evaluate themselves the validity of the claim. Advertising with the physician has been almost completely unrestricted, even to quite misleading information, because it was felt that the physician could stand between the advertising and the ultimate consumer.

I would like to submit that with a drug a day coming out and with the volume of advertising and journal literature that this is no longer possible, that the physician cannot stand between the advertising and the patient, and it may be that the advertising to the physician will have to be looked at more in the light of the advertising to the individual who cannot re-evaluate. I don't mean this to be impinging on the ability of the medical profession but simply they have been in my experience quite overwhelmed with the volume with which they have to cope."

(Hearing, pp.557-58)

It is clear that the implementation of the measures proposed above would necessitate a substantial enlargement in the staff of the Food and Drug Directorate.

The third method of reducing the volume of expenditures on advertising and promotion consists in the development and improvement of alternative methods of disseminating information on new drugs. As stressed in the Final Report of the Hinchliffe Committee (see section 1 of Chapter XIII), this could be achieved in part by the organization by Canadian medical schools of refresher courses, post-graduate seminars or lectures for general practitioners at which the merits and demerits of new drugs could be studied. In the field of governmental action, sponsorship by the federal government of a publication giving an objective evaluation of new drugs would improve the present situation substantially.

7. Effect of Sales Tax on Prices of Drugs

One of the proposals most frequently urged upon the Commission was the exemption of all drugs from the 11 per cent Canadian sales tax. Under the Excise Tax Act (1), the only drugs now exempted are the items listed in Schedule III. They include principally insulin, cortisone, poliomyelitis vaccine and also drugs sold to hospitals, not for resale.

It is possible that the removal of the sales tax on drugs would have a substantial effect upon prices. As shown in Chapter XV, retailers and wholesalers normally receive discounts off the suggested retail prices of 40 per cent and of 40 and 16 $\frac{2}{3}$ per cent respectively. In the case of a drug with a retail price of \$1.00, a price to the retailer of 60¢, and a price to the wholesaler of 50¢, what would be the effect of the removal of the sales tax? The manufacturer's price of 50¢ to the wholesaler includes the sales tax. If the sales tax were removed the manufacturer could reduce his price by $\frac{11}{111}$ of 50¢ (about 5¢) and still make the same gross margin as previously. It is reasonable to think that the manufacturer would reduce his price to 45¢. Assuming the same percentage relationships to continue between prices at the several trade levels, the retail price to the consumer would become 90¢, and the price to the retailer 54¢. Looking at the situation in reverse, as is usually done in preparing price

(1)

Appendix H to this Report, Excise Tax Act, s.32(1).

lists, the list price would be 90¢, the price paid by the retailer 40 per cent less or 54¢, and that paid by the wholesaler 16 $\frac{2}{3}$ per cent less than 54¢ or 45¢.

This is what might be expected to happen, subject to the following possibilities:

1. The manufacturer might not reduce his price at all. In this case there would almost certainly be no reduction at any level. However, it is not likely that one or some manufacturers would adopt this course unless all or nearly all did so, and this might be difficult to explain in the absence of collusion. The reasonable expectation is that the manufacturer's saving would be passed on.

2. While reducing his own price, the manufacturer might revise his list prices so as to allow the wholesaler and retailer larger percentage margins than the traditional ones stated above. This would permit the wholesaler and retailer to maintain in whole or in part their gross margins in dollars and cents.

3. Notwithstanding that the manufacturer revised his price lists to show a consumer price of 90¢, a price to the retailer of 54¢ and a price to the wholesaler of 45¢, the wholesaler and retailer might not follow these prices, but increase their margins percentage-wise so as to maintain the same gross margin in dollars and cents as hitherto. This course seems unlikely for the retailers, in view of their long established practice of adopting the manufacturer's list price.

If none of these three contingencies should occur, the net result to the consumer of the removal of the sales tax would be a reduction in price from \$1.00 to 90¢ or 10 per cent. For many drugs this would bring Canadian prices down to a level approximately equal to those prevailing in the United States.

But the Combines Investigation Act limits the Commission's terms of reference. They do not extend to inquiries into whether prices, simply as prices, are high or low. This inquiry is limited to considering whether there is evidence of a monopolistic situation or of restrictive practices in the industry, which situation or practices, if they exist, might of course have an effect on prices. There is no evidence before the Commission tending to show, and the Commission does not believe, that the existence of the sales tax has or would be likely to have any bearing upon any monopolistic situation or restrictive trade practice that might possibly be found to exist in the industry. We therefore make no recommendation with respect to sales tax. In our opinion this question is one of government policy entirely outside our terms of reference.

8. The Purpose of the Dumping Duty Provisions and
their Operations with Respect to Ethical Drugs

Like the sales tax, customs duties are outside the terms of reference of the Commission. For this reason, the Commission does not make any recommendation in regard to them. However, it is considered that some reference should be made to the special dumping duty provisions, as it was suggested that in some circumstances they had a particular effect on prices (1). These provisions are certainly intended to protect Canadian manufacturers of goods of the same class or kind as those imported from being undercut by unfairly low prices of imported goods. With this in mind, the Commission has examined how they operate with respect to ethical drugs and more particularly antibiotics and tranquillizers.

Dumping duties are applied to drugs which are considered to be of a class or kind made in Canada, when the price charged the Canadian importer is less than their fair market value in the country of origin. The amount of the duty is the difference between the two. When there is an established market for the imported drugs in the country of origin, the prices at which the drugs are sold in such market determine the fair market value. When there is no such market -e.g., when the drugs are imported as raw materials, or in a partly manufactured state, or unpackaged, or unlabelled, but sold in the country of origin as finished products only; or when they are sold in the country of origin to wholesalers or retailers only and imported as finished products by a Canadian manufacturing firm; or when the foreign exporter has manufactured or bought a very large quantity of the goods and the Canadian importer has bought a relatively small portion thereof - in all such cases the value for duty is determined in such manner as the Minister of National Revenue prescribes under section 38 of the Customs Act. (2)

As shown in section 2 of Chapter IX and section 1 of Chapter XIX, the dumping duty provisions, when applied to dealings between parent and subsidiary companies, sometimes lead either to higher prices for drugs being charged in Canada than in the country of origin or to a distortion in the profit ratios of the companies concerned. This situation arises when a drug is sold in the country of origin to wholesalers or retailers only and imported as a finished product by the Canadian manufacturing subsidiary of the exporting company. In such a case, the fair market value is determined by

(1) Customs Tariff, s. 6.

(2) R.S.C., c. 58, s. 38, as amended by S.C., 1958, c. 26, s. 1.

prices to wholesalers or retailers in the country of origin and prices at the corresponding level will be higher in Canada than abroad to the extent of the mark-up taken by the Canadian subsidiary for its own operations. To the extent that the latter's mark-up is less than would normally be taken, the profit ratios of the parent and the subsidiary are distorted. Even in an extreme case where the latter operates at a loss, one would expect the over-all operations to be profitable and the profit realized by the parent to more than offset the loss taken by the subsidiary.

The Commission was informed that dumping duties are seldom imposed on drugs. A United States company, not familiar with the Canadian dumping duty rules, might find a first shipment had been subjected to payment of dumping duty, but would never have its shipments caught a second time. The practice of most American companies, when they intend to supply some new drug products to their Canadian subsidiaries, is to approach the Canadian Customs Department, tell the facts and ask that the fair market value in the United States be fixed. The Canadian subsidiary is then charged a price which is at least as high as the determined fair market value and may well be higher than the price the Canadian subsidiary would have been charged in the absence of the dumping duty rules. When this is the case, the effect of the application of the dumping duty rules to imports of drugs is to put extra money into the pocket of the United States exporter, not into the Canadian Treasury.

To what extent are Canadian manufacturers of ethical drugs, and more particularly of antibiotics and tranquillizers, actually protected by the dumping duty provisions? As shown in the Green Book (para.112, page 63), the drug manufacturing industry in Canada is very largely in the hands of subsidiaries of foreign companies, of which the great majority are United States companies. Since the purchase of Frank W. Horner Limited by Carter Products Inc., Charles E. Frosst & Co. is the only independent Canadian firm at all comparable in size to any of the larger United States subsidiaries in this country. At the time of the hearings, very little manufacturing of basic antibiotic or tranquillizing drugs was done in Canada. The great majority of basic drugs of these kinds was imported, Canadian manufacturing being mainly confined to refining, preparing dosage forms and packaging. A substantial amount of finished dosage forms of some of these drugs is imported, but the Commission has seen no clear evidence as to what proportion of the drugs comes into Canada either in partly finished form, or in fully finished dosage forms in bulk, or packaged and labelled ready for resale. Moreover, at the time of the hearings, some changes were taking place in this situation. For example, the Commission was informed that Cyanamid of Canada Limited was expanding its facilities for the basic fermentation of certain antibiotics in Canada (Cyanamid brief, p.5).

The American manufacturers who export most of these drugs to Canada exercise close control over them in the United States through patents. In United States law, patents apply to the product as well as to the process of manufacture and there is no provision similar to the compulsory licensing rule found in section 41(3) of the Canadian Patent Act. In the case of many antibiotics and tranquillizers, the Canadian subsidiaries of these American firms may be the only ones to sell at the manufacturing level in Canada, because little use has been made in this country of the compulsory licensing provisions. In spite of this, the dumping duty provisions apply, because another drug considered to be of the same class or kind is made in Canada.

For purposes of the dumping duty provisions, each group - the antibiotics and the tranquillizers - is considered as a class. As at least one tranquillizer, meprobamate, and one antibiotic, chloramphenicol, are made in Canada, all tranquillizers and antibiotics are subject to the application of the dumping duty rules, when imported in dosage forms. However, the Commission was informed that antibiotics may be exempted when imported in bulk as basic drugs, if they are to be used in the manufacture of some pharmaceutical compounds not regarded as being of the same class or kind as any antibiotic manufactured in Canada.

This is a field, however, where the price elasticity of demand is indeed very low. It is clear that doctors are primarily concerned with prescribing the drugs that will be most effective in treating their patients' diseases. They are only secondarily concerned with the cost of the drugs. Whatever may be said about all tranquillizers being of the same class or about all antibiotics being of the same class, prescribing physicians do not appear to regard all drugs in each group as therapeutic equivalents. Were it not for sales to hospitals and governments, the same might be said about two brands of the same drug, as long as the great majority of prescriptions are written with brand names.

In view of the foregoing circumstances the Commission inclines to the view that, with respect to ethical drugs and more especially antibiotics and tranquillizers, the dumping duty rules may sometimes operate to increase the costs of some Canadian importers without giving any substantial protection to Canadian manufacturers.

9. Advisability of Issuing Compulsory Licences
as of Right

The Canadian law relating to patents on drugs is discussed in Chapter VI.

There can be no doubt that Parliament enacted subsections (1) and (3) of section 41 of the Patent Act in the interest of public health. Under section 41(1), a pharmaceutical product may be patented if produced by a process other than a chemical one, but whenever the process of manufacture is chemical, a patent can be obtained only for the process or for the drug when produced by that process. Thus a drug produced by a chemical process receives less protection than those produced by other processes. When a drug made by any process, chemical or other, is subject to patent protection, a compulsory licence to manufacture such drug can be obtained under section 41(3) at any time on application to the Commissioner of Patents unless the Commissioner sees good reason not to grant the licence. The subsection further provides that in fixing the royalty payable under the licence the Commissioner shall have regard to the desirability of making the medicine available to the public at the lowest possible price consistent with giving to the inventor due reward for the research leading to the invention.

One would expect to find competitors eagerly seeking licences in a period when many new drugs have been coming on the market, some of which have marked great advances in the treatment of certain types of disease, and many of which have found wide acceptance and enjoyed very substantial sales. The prospect of profit should lead to such activity. What has been the actual situation? From 1923, when the special compulsory licence provision was enacted, to 1949 only one application was made for a compulsory licence. From 1949 to January, 1963, 22 applications were made. Of these, 2 were withdrawn and 2 have not been proceeded with. Indeed the foregoing record indicates that the compulsory licensing provisions have been put to very insignificant use.

In his evidence before the Commission (Hearing, p.296), Mr. J.W.T. Michel, the Commissioner of Patents, stated that only one application had ever been refused. It was an application for a licence to import, not to manufacture. As a rule, therefore, there appears to be no serious difficulty in the path of an applicant. Up to 1959, however, there may have been some uncertainty about the right interpretation to be given to section 41(3). In that year the Supreme Court of Canada ruled that section 41(3) applied to the product when

produced by a chemical process as well as to the process itself. (1)
The uncertainty that may have prevailed up to the time of this decision may have contributed to the view that an application for a compulsory licence would be a lengthy matter at best and might lead to expensive, long drawn out litigation of which the outcome would be doubtful. For this reason, the Commission tried to ascertain whether the decision referred to above resulted in some increase in applications for compulsory licences. There were 8 applications from 1949 to July, 1960 and 6 in the next twelve months, but of these 6, 2 have since been withdrawn and 2 have not been proceeded with. Since July 1961, 8 more applications have been made, but none has yet been disposed of. It appears, therefore, that some increase has occurred in the number of applications, but in view of their subsequent history the increase cannot be regarded as significant.

It may be argued that the compulsory licensing provisions induce the patent holders to grant licences on a voluntary basis. The Commission has no means of ascertaining the number of voluntary licences, but the survey conducted by the C.Ph.M.A. indicates that the number is quite small in comparison with the number of manufacturing companies and the number of successful new drugs. With respect to this matter, Mr. J.W.T. Michel stated that there is still a marked tendency on the part of foreign companies holding Canadian patents to object strenuously to the granting of licences (Hearing, p.302). Apart from cross licensing arrangements arising out of conflicting patent claims of 2 or more companies, there appear to have been no voluntary licences granted in respect of the five most important broad spectrum antibiotics. (2) The position is almost the same for the newer penicillins, the tranquillizing or ataractic drugs and the corticosteroids. It is significant that it is precisely these four categories of drugs that have had the greatest impact upon the market during the last twelve or fourteen years. A number of them have had very large sales and have earned great profits for the patent holders. For these reasons, the Commission does not consider that the small number of applications for compulsory licences can be explained by the willingness of the patent holders to grant licences on a voluntary basis.

Section 8 of Chapter VI outlines several reasons advanced by the drug manufacturers to explain the negligible use made hitherto of the compulsory licence. All of these may have some bearing on the

(1)

Parke, Davis & Company, Ltd. v. Fine Chemicals of Canada Limited, 30 C.P.R., 59.

(2)

There is one exception to this statement. Very recently a licence for chloramphenicol was granted by Parke, Davis & Company Ltd. to Gilbert & Company as one of the terms of settlement of an infringement action. See "P.D. Announces Settlement of Patent Infringement Suit", Canadian Pharmaceutical Journal, Vol. 95, No.12, December 1962, p.565.

matter, but, in so far as they are valid they all point to the conclusion that the inventor of a new drug does not need patent protection, because for a variety of reasons competitors either would not or could not successfully enter the field. One very probable explanation is suggested in the Green Book (pp.224-25):

"395. . . . Most of the large ethical drug firms in Canada are subsidiaries or branches of foreign companies, many of which carry on world-wide operations. These firms have developed their own specialties which they promote in whatever countries they do business. It may not be considered practical for such a firm to obtain a compulsory licence which would only allow it to manufacture and sell a particular drug in Canada. If it did so, its Canadian subsidiary or branch would have to develop and market the product on its own in competition with established brands of manufacturers which would, for example be advertised in the United States technical and scientific journals which reach Canadian doctors. It does seem to be significant that the few compulsory licences issued under section 41(3) of the Patent Act have been obtained chiefly by wholly Canadian firms."

Since 1949, there have been 18 applications for a compulsory licence, if withdrawn or dormant applications are not counted. Of these 18, none was made by any of the large United States or European companies or their subsidiaries; 2 were made by Canadian subsidiaries of small American firms, 2 by large Canadian companies, and the other 14, by small purely Canadian companies.

The issue of a patent is designed and intended to give the patentee a temporary monopoly. However, section 41 of the Patent Act, and more particularly subsection (3) thereof, is designed and intended, in so far as drug patents are concerned, to make competition possible, so that the drug will be available to the public at the lowest possible price consistent with due reward to the inventor. In the Commission's opinion there are grounds for serious doubt that this latter purpose has been attained.

In the first place, the almost negligible direct use of subsection (3), together with what the Commission believes is the relatively small number of voluntary licences granted, indicate that this subsection has not been the cause of much competitive activity. Secondly, Chapter XXII outlines several instances in each of which a drug, made by the same company in both Canada and a foreign country, had been purchased at retail in the foreign country and imported to Canada at a landed cost, after paying freight, customs and taxes, very much lower than the price at which it could be obtained

in Canada. The Commission understands that costs, e.g., of advertising and promotion, are substantially lower in these other countries than in Canada, but the price differentials were sufficiently great that some further explanation appears to be required.

It was strongly argued before the Commission that all the broad spectrum antibiotics were in close competition with the penicillins and even with the sulphonamides and that the same situation existed between the tranquillizers and the barbiturates. In fact it was contended that every drug offered for sale was subject to intense competition.

Undoubtedly there is keen competition, particularly among the larger, well established companies with adequate research facilities, to bring out new or improved products, although very little of this development effort is carried on in Canada or by Canadian companies. There is also, among these companies, keen competition in advertising and promotion of their products. On the other hand, in respect of drugs protected by patent and manufactured by only one or a very few companies, it is difficult to see that competition operates so as to force down prices till they show only a modest profit over costs, either shortly after the appearance of the drug or some years later.

When a new drug first appears on the market it is not to be expected that its price will be related to production costs. This is particularly true of patented drugs. As Professor Dixon said, in the first instance price is oriented to demand. This means that the company sets the price at a level which, in view of all market conditions, including the volume of sales anticipated at that price, will produce the best return. The company quite naturally desires to recoup its research costs and its initial advertising and promotion costs as quickly as possible because of uncertainty as to acceptance and market life of the drug. Consequently the common experience is that the price of a new drug is quite high in comparison with production costs. This is perfectly normal and reasonable practice.

What has given the Commission some concern is the later history of prices of drugs as indicated in the Green Book, Chapter XV. In respect of the older penicillins, for which no patents were obtained, and the streptomycins, for which licences were freely given, prices soon began to decline and over a period of some years reached a level that appears to have been very close to costs. However, in respect of later drugs controlled closely by patents, notably the five broad spectrum antibiotics, the story is quite different. Chlortetracycline (Aureomycin), chloramphenicol (Chloromycetin) and oxytetracycline (Terramycin) came on the market in Canada successively within a year

or two, beginning in May 1950. Price reductions occurred down to 1953, due largely to improvements in methods of production. From 1953 till late in 1960 no reductions occurred. When Cyanamid introduced tetracycline (Achromycin) in 1953 and demethylchlortetracycline (Declomycin) in 1959 it adopted the prevailing price of the three earlier broad spectrums. When price reductions did occur late in 1960 there may have been several contributing factors, but the Commission is of the opinion that the lower prices of imported European drugs constituted the most important one. During the intervening years, notwithstanding that all of these drugs enjoyed large sales and that the costs of both basic drugs and finished dosage forms showed remarkable variations between companies, no company thought it desirable to reduce its prices. It was as if the price established in 1953 had come to be regarded as the right price.

It was submitted on behalf of the manufacturers that essentially identical prices for these drugs, such as have prevailed since their introduction, are not a mark of close control but represent exactly the result to be expected from active competition. The Commission, however, does not find this argument convincing, when applied, as it is here, to a market in which the manufacturers have widely varying costs and in which those responsible for consumer purchases, the prescribing doctors, evince a very strong loyalty to products they have come to know and have used with satisfactory results. The Commission's view is strengthened by the fact that the prescribing physician does not pay for the drug and, according to the evidence before us, not only is primarily concerned with obtaining the most effective drug for his patient but very frequently does not know either the price of the drug he prescribes or those of alternatives.

It is the Commission's opinion that close control exercised by patents has made it possible to maintain prices at levels higher than would otherwise have obtained. The meagre use made of the compulsory licensing provision in section 41(3) of the Patent Act has meant that competition from rival producers of the same patented product has seldom occurred and thus has had little or no effect on prices. In the light of this situation, it becomes necessary to consider what steps may be taken to secure the objective of section 41(3) to a substantial degree.

The Commission considered the advisability of making compulsory licences issuable as of right. In the absence of offsetting factors one might expect that this measure would make compulsory licences more valuable by shortening the period of time required to obtain them and thus lead to greater use of the provision. In his evidence to the Commission, Mr. J.W.T. Michel stated that under the present procedure a minimum of seven to eight months was required. However, it usually takes more than that. Of the 8 applications that

were pending on January 23, 1963, 6 were older than nine months, and only one of these 6 had reached the stage of the hearing before the Commissioner. If compulsory licences were issuable as of right, long delays would be obviated because the Commissioner of Patents would no longer require evidence or argument to determine whether there was "good reason to the contrary". This question would not arise. The only problem that would have to be settled is the amount of the royalty. This time-saving feature might well lead to a significant increase in applications for compulsory licences. If so, the purpose of section 41(3) might be substantially attained.

Objections have been made to making compulsory licences issuable as of right. It is argued that the compulsory licence in its present form already cuts down the advantage normally given to a patent holder because any number of licences may be ordered unless the Commissioner "sees good reason to the contrary", giving the patentee only the small returns from royalties instead of the much larger profits he could gain if he could retain his exclusive right of manufacture and sale. To make compulsory licences obtainable as of right would reduce the already short period of time during which the delays arising under the present section 41(3) give exclusive rights in practice. The prospect of smaller profits would reduce the incentive to engage in research.

Against these arguments must be set the fact that very little use has been made of section 41(3) down to the present time. Consequently the patent-holding companies have not suffered to any serious extent from the incursions of compulsory licencees. In fact for most of the important drugs no compulsory licences have ever been issued. Any increase in applications for licences which might be expected to result from making licences obtainable as of right, would, of course, by increasing competition, tend to reduce the control exercised over prices through patents. Any ensuing price reductions would be beneficial to the public and would constitute a movement bringing prices more nearly into line with the declared purpose of section 41(3) of the Patent Act. Bearing in mind that, with few exceptions, very little research is carried on by or at the expense of drug companies in Canada, the implementation of this proposal would have a negligible effect upon research activities in this country.

On the advisability of making compulsory licences issuable as of right, the Royal Commission on Patents, Copyright and Industrial Designs, hereinafter referred to as the Ilseley Commission, reached the following conclusions as stated in its Report on Patents of Invention:

"We considered whether we should recommend that the section provide for licences of right so that the Patent Tribunal would not be concerned with the question whether 'there are good reasons for refusing the application'. One of the objections to leaving this question of good reasons to the Patent Tribunal is that lengthy arguments may result, entailing delay and expense.

However, on the whole, and on balance, we think that it would be desirable to continue, for the time being at least, the principle contained in subsection (3) of section 41 of our present Act that licences shall not be of right but that the licensing authority may, if good reason to the contrary, or good reasons for refusing the application, are established, refuse to grant the licence. This principle is embodied in section 41 of the United Kingdom Patents Act of 1949. The guidance the courts have given as to what may be regarded as good reasons for refusing the application is decidedly [sic] vague, and perhaps necessarily so, as the future situations which may arise are unpredictable and almost infinite in number. Circumstances can readily be imagined where the licensing authority might reasonably consider that in the public interest the licence should not be granted. It occurs to us that this would normally be so if it were established that there was a probability that the granting of the licence would result in an increase rather than a decrease in the cost of the food or medicine to the public, or that the applicant had no bona fide intention of embarking upon the production of the food or medicine. There may be other circumstances the proof of which before the Commissioner would point to the conclusion that the granting of a licence would not be in the public interest which do not suggest themselves to us, at least in a form which would enable us to express them without complex qualifications.

One disturbing possibility is that delaying tactics on the part of patentees who oppose applications for compulsory licences will develop. In view of the possibility of large profits on some patented foods and medicines, particularly drugs, the field is such that a substantial delay may be of great financial advantage to the patentee. With respect to the possibility of such delays we make the following recommendations:

(1) That rules be made having as their purpose the complete disposition of every application, at least up to the time of the fixing of the royalty (if the application is granted) within three months after proof of service of notice of the application upon the patentee. These rules could provide for completion of all representation within a certain

time after the beginning of the proceedings and might provide that the application, in the absence of a disposition of the matter before the period of three months after proof of service of the initial notice, shall be deemed to be granted, the only matter remaining being the fixing of the royalties. Exceptions may have to be made providing for such contingencies as vacations, illness of the judge constituting the Patent Tribunal, and vacancies in that position.

(2) That it be provided by rule that the representations may be wholly in writing, the Patent Tribunal having a discretion to require oral submissions. We understand that this is the practice now followed by the Commissioner: Fine Chemicals of Canada Ltd. v. Parke, Davis & Company decided by the Commissioner on April 1, 1959, in respect of which an appeal was dismissed by the Exchequer Court (Case No.154512) on October 2, 1959, leave to appeal to the Supreme Court of Canada refused; Delmar Chemicals Limited v. American Cyanamid Company decided by the Commissioner, September 14, 1959.

(3) That if it is found, notwithstanding the foregoing that there are serious delays, considerations be given to amending the section so that licences will be issuable as of right." (1)

If the patent system should continue to be applied to drugs, it would be advantageous to implement the above recommendations. Except perhaps for the fixing of the royalty, every application should be completely disposed of within three months after proof of service of notice of application upon the patentee. This Commission believes that, if this result is not generally obtained, compulsory licences should be made issuable as of right to any licensed drug manufacturer. Indeed, if as recommended in section 3 of this chapter, all drug manufacturers were required to be licensed, one major objection to the issuance of compulsory licences would no longer exist, for any licensed drug manufacturer might be deemed to be a competent applicant.

However, even if compulsory licences were made issuable as of right, it seems likely that only small Canadian companies would take advantage of the compulsory licensing provisions to any significant extent. Though some increase in applications might be anticipated

(1)

Royal Commission on Patents, Copyright and Industrial Designs, Report on Patents of Invention, December 31, 1959, pp. 96-97.

the Commission's study of conditions which have developed and prevailed under the present provision leads it to the conclusion that such a change would not alter in any substantial way the degree of control over drugs and drug prices now exercised through the medium of patents. Whatever results might follow would be merely palliative, not truly remedial. To secure results of the latter kind it would appear necessary to go further and remove patent control from drugs.

10. Abolition of Patents on Drugs

The Report on Patents of Invention recommended that the general patent system be retained. The Ilsley Commission, after reviewing the arguments of economists in the United States and Great Britain for and against the continuance of the patent system, adopted the view of Fritz Machlup ⁽¹⁾ in the following words:

"On the whole, we have come to the conclusion that even to Canada with its large preponderance of foreign owned Canadian patents the words in the concluding passages of Fritz Machlup's study apply - 'if we did not have a patent system it would be irresponsible, on the basis of our present knowledge of its economic consequences, to recommend instituting one. But since we have had a patent system for a long time, it would be irresponsible, on the basis of our present knowledge, to recommend abolishing it'." (2)

This language certainly does not constitute a strong endorsement of the patent system on its merits. The Royal Commission was obviously somewhat impressed by some of the economic arguments pointing to disadvantages of the patent system, and particularly by Professor Machlup's words immediately preceding the passage quoted above:

"No economist, on the basis of present knowledge, could possibly state with certainty that the patent system, as it now operates, confers a net benefit or a net loss upon society. The best he can do is to state assumptions and make guesses about the extent to which reality corresponds to these assumptions.

(1)

Fritz Machlup, Study 15 prepared for the O'Mahoney Subcommittee of the Committee on the Judiciary, United States Senate, pp.79-80.

(2)

Royal Commission on Patents, Copyright and Industrial Designs, op. cit., p.15.

If one does not know whether a system 'as a whole' (in contrast to certain features of it) is good or bad, the safest 'policy conclusion' is to 'muddle through' - either with it, if one has long lived with it, or without it, if one has lived without it. . . . "

The Report on Patents of Invention ⁽¹⁾ quotes the following passage from Mrs. Edith T. Penrose:

"Any country must lose if it grants monopoly privileges in the domestic market which neither improve nor cheapen the goods available, develop its own productive capacity nor obtain for its producers at least equivalent privileges in other markets. No amount of talk about the 'economic unity of the world' can hide the fact that some countries with little export trade in industrial goods and few, if any, inventions for sale have nothing to gain from granting patents on inventions worked and patented abroad except the avoidance of unpleasant foreign retaliation in other directions. In this category are agricultural countries and countries striving to industrialize but exporting primarily raw materials." ⁽²⁾

The evidence collected in this inquiry does not show that patents have either cheapened the drugs available in Canada or improved them in any way. Productive capacity in Canada has definitely increased, but bearing in mind the great increases that have occurred in Italy, where there are no drug patents, it appears likely that Canadian productive capacity might have grown without patent protection, perhaps even at a faster rate than has occurred. Canadian producers have, in International Convention countries, whatever privileges those countries give their own nationals, which may or may not be the same as those granted in Canada by patents to nationals of those countries. Finally the Commissioner of Patents stated in evidence that with respect to Canadian patents generally the percentage held by Canadian residents was less than six per cent and in respect of drugs it was definitely less than that (Hearing, p.310). It is therefore clear that Canada has very few drug inventions for sale. This has been the situation for many years and the Commission sees nothing in the evidence which suggests there is likely to be any significant change. The Commission has no complete information as to the volume of Canadian exports of patent protected drugs, but from the figures for 1958 contained in Table XLIII of the Green Book it would not appear to be large. For these reasons Canadian drug patents appear to have conferred substantial economic advantages on patentees, nearly

(1)

Ibid., p.15.

(2)

Mrs. Edith T. Penrose, The Economics of the International Patent System, 1951, pp.116-17.

all of them foreign. Only a handful of Canadians have received similar benefits therefrom.

Mrs. Penrose's comments, though made in relation to industrial patents generally, have pointed significance when applied to the drug industry in Canada. The same may be said of the following passage, also quoted in the Report on Patents of Invention, (1) from a research study prepared by Dr. Vannevar Bush at the request of the O'Mahoney Subcommittee of the Committee on the Judiciary, United States Senate:

"First, it [the Patent System] aims to stimulate both invention and the assiduous search for new applications of knowledge, which is the basis of invention. It does this by placing the inventor in a position to secure a reward.

Second, it seeks to create conditions whereby the venture of funds to finance the hazardous introduction into public use of new devices or processes will be warranted. This is done by protecting the industrial pioneer for a limited time against the uncontrolled competition of those who have not taken the initial financial risk.

Third, it aims to prevent the creation of an industry permeated by the intense secrecy with regard to its processes which characterized the medieval guilds and which can only retard the realization by the public of the benefits of scientific progress. This it does by extending a temporary monopoly to those who, in keeping with the American ideal of openness and frankness, will make a full disclosure of their new ideas so that they may be utilized to the full by those skilled in a particular art." (2)

The Commission has examined whether the three great objectives of the patent system, referred to in the above quotation, are attained in the special circumstances of the Canadian drug industry. Let us consider these three objectives in reverse order.

(1)

Royal Commission on Patents, Copyright and Industrial Designs, op.cit., p.11.

(2)

Dr. Vannevar Bush, "Some Proposals for Improving the Patent System", p.1.

It is the opinion of the Commission that no substantial benefit flows from the fact that discoveries are disclosed to the Canadian Patent Office. As stated by Mr. J.W.T. Michel in his evidence (Hearing, pp.310-11), most discoveries are made abroad, and patented in the country of the inventor. For this reason, when they are filed in Canada they have already been made known to the world or at least knowledge of them has been made available to all interested persons. Moreover there is some evidence to the effect that, with respect to the manufacture of drugs, know-how is of paramount importance. Dr. C.H. Best, one of the Directors of the Connaught Laboratories, stated that in some matters the sharing of "know-how" was more important than the technical disclosures required by the patent itself. He referred to a case where several million dollars had been asked for "know-how". It is also significant that, in an action against former employees charged with having sold samples of complex cultures and secret techniques to several Italian firms, American Cyanamid estimated its damages at \$5,000,000. (1) In the light of such circumstances, it is clear that the patent system does not prevent the creation of an industry permeated by intense secrecy with regard to its processes.

Secondly, the Commission does not believe that the issuance of Canadian patents on drugs is a prerequisite for the investment of the necessary funds in new lines of production which would otherwise appear unprofitable. Most new drugs are developed either in the United States or in Europe and whatever protection the Canadian Patent Act might grant has by itself no significant effect on the introduction of these drugs in Canada.

Finally, for the reasons outlined below, the Commission considers that the existence of patent protection on drugs does not and is not likely to stimulate materially research and invention in Canada:

1. Canadian patents on drugs are secured to an overwhelming extent by patentees resident in foreign countries. Research in the drug field carried on by large drug companies on this continent is done largely in the United States. (2) Research and development activities are concentrated there because the drug firms have found that research is more efficiently done when concentrated than when dispersed.

(1)

The Gazette, "Canadian Go-Between in Drugs Pirating Uncovered in U.S.", Wednesday, July 18, 1962, p.1.

(2)

The Commission understands that the Ayerst, Frosst and Horner companies have good research facilities. Formerly all three were purely Canadian companies, but today Frosst is the only one independent of American control.

2. In the foreseeable future it seems very unlikely that the Canadian subsidiaries of American parent companies will establish important research facilities in Canada. Cyanamid's brief (pp.45-47), presented by Mr. R. B. Thompson, did refer to research facilities that had been built by American Cyanamid in Switzerland, and stated that their parent company had indicated its willingness to decentralize its basic research activities. Trained scientists are in short supply and it is becoming necessary for research facilities to be taken to places where scientists are living. Canadian technical and scientific talent are highly regarded. The brief ended, however, by stating there are obstacles to be overcome before commercial research could be embarked upon to any marked extent in Canada, and to this end supported the recommendation of the Ilsley Commission (1) that patent protection be extended to include products as well as processes (Cyanamid brief, pp.45-47; Hearing, pp.1532-35). The predominant impression left with the Commission by the evidence as a whole is that research would tend to remain concentrated for many years to come. Although expenditures on research by Canadian subsidiaries of American companies have increased in recent years, this has been due largely to recent regulations of the Food and Drug Directorate which require an increasing amount of clinical testing of new drugs in Canada prior to approval by the Directorate.
3. The main Canadian research contributions that have been made in the field of drugs have resulted almost entirely from non-commercial activities at places like the Connaught Laboratories.
4. Although it is strongly contended by the drug industry that the patent system is the necessary spur to research and development in the drug field, it is far from clear that patents are the sine qua non of major advances in this area. The United States has always had full product patent protection, but it is only in the last twenty years or so that discovery and development of new drugs in that country have placed the United States well in the forefront of countries in this field. Most European countries have process patents but not product patents. Many of them

(1)

Royal Commission on Patents, Copyright and Industrial Designs, op. cit., p.94.

have made notable pharmaceutical discoveries. For example, penicillin was discovered and the basic research thereon was carried out in England, which at that time had no product patents. Similarly, in Germany, Denmark, Switzerland and other countries where processes but not products are patentable, much fundamental as well as developmental research has been carried on over the years, and many new drugs have made their first appearance in those countries. Even with respect to Italy, where the present day industry is apparently quite new but growing rapidly, where there are no drug patents at all, and whose manufacturers are often accused of merely imitating or even pirating products discovered and developed by others, the situation is not clear. The Commission has had no first-hand evidence. Mr. Thompson of Cyanamid of Canada, in giving evidence on October 16, 1961, stated that the research director of American Cyanamid, who was very interested in the Italian situation, had told him a few days previously that not one new drug of any consequence had been developed in Italy since the patent law was abrogated (Hearing, p.1571). This apparently, though inaccurately, refers to Mussolini's enactment in 1934. On the other hand, the Kefauver Report mentions a number of new drugs, described as possibly significant, of varied types and uses, which it states the Italian drug industry has developed. ⁽¹⁾ Further, the December 1962 issue of the Canadian Pharmaceutical Journal has a reference to Italy which includes a statement that many Italian pharmaceutical firms have reached international status and have had to expend large sums in research in order to compete in world markets.

In the light of the available evidence of what has transpired in other countries the Commission is of the opinion that lack of product patents does not explain the general low level of research activity carried on in Canada by drug manufacturers. On the same evidence the Commission inclines to the view that the abolition of patents, while it might possibly have some effect upon future research developments, would neither eliminate the limited amount of research now being carried on nor prevent further research being undertaken in the future.

5. Some of the evidence before the Commission suggests that there is a fairly prevalent opinion in the industry, both here and in the United States, that so far as new drugs are concerned the industry has reached a plateau, that no really important new drugs have appeared on the scene

(1) Report of the Committee on the Judiciary, United States Senate, Made by its Subcommittee on Antitrust and Monopoly, U.S. Government Printing Office, Washington, 1961, p. 135.

since about 1955, and that a big new break-through is required if drug therapy is to resume its advance. In 1960, trade papers of the American drug trade began to refer to a "research gap", i.e., a dearth of new products.

Drug manufacturers, as businessmen, naturally tend to pick up a discovery arising from fundamental research, and to concentrate their own research on refining and developing the original chemical discovery for the purpose of obtaining in the end beneficial new drugs which can be patented and placed on the market with profit to themselves. A very high proportion of their research activities has been of this kind, rather than original fundamental research. Perhaps because of the large profits a number of companies have obtained by developing new drugs in this way, e.g., by making minor modifications of molecular structures, manufacturers have tended to neglect original research. This may have some bearing on the scarcity of important discoveries in recent years. Certainly Mr. Thompson of Cyanamid expressed it as his opinion that greater emphasis on basic research was required and was coming about.

6. The patent system, by placing a profit premium on the development of minor modifications of existing drugs which can be patented, is at least partly responsible for the appearance on the market of many drug preparations of slight value or even questionable merit.
7. The abolition of patents in Canada would have no effect upon research activities in the United States, where practically all the research by United States parents of Canadian subsidiaries is carried on. Similarly, though proportionately of less importance, it would have no effect on research activities in European countries, some of it by parents of Canadian subsidiaries. The results of such research would not be withheld from Canada.

The Ilsley Commission pointed to the relevance of the foregoing observations to conditions in Canada, but, as already mentioned, that Commission came to the conclusion that Canada, having had a patent system for a long time, should not abolish it. This Commission believes that there are special circumstances attached to the drug industry in Canada which suggest that a different conclusion may be right in respect of drugs than that reached by the Ilsley Commission concerning patents generally.

It is the conclusion of this Commission that the control over drugs exercised through patents in Canada is disadvantageous to the users of drugs in this country by enabling the suppliers of such drugs to charge high prices in relation to the cost of production and distribution of the medicines. The Commission did not find any advantages to Canada from the patent control of drugs which would offset, in any significant degree, the disadvantage to the Canadian public nor does it consider that there would be any change in this situation in the foreseeable future if the patent system continued to apply to drugs. In view of these circumstances the Commission believes that the only course likely to provide a remedy for the detriment resulting from drug patents is their abolition.

The abolition of patents as applied to drugs as a unilateral action by Canada might be regarded as a means of securing for this country the fruits of research and invention in other countries without our making any contribution to the cost of new drugs. In a narrow sense this might be considered as one of the results of the abolition of patents relating to drugs in Canada inasmuch as no royalties would be payable to the inventor by any firm making use in Canada of discoveries disclosed under patents in other countries. However, this is only one aspect of the reward which a drug manufacturer may secure from the successful development and promotion of a new drug. If a large market is quickly established for the new product the innovating company will gain the benefits of having that market to itself until other producers are successful in gaining significant shares. This interval of time may extend for a considerable period if "know-how" is an important element in the production of the new drug and is of such a nature that outside firms cannot acquire it without considerable delay for experimentation and trial. Another factor of considerable importance is the regard held for the innovating manufacturer by the medical profession. If the manufacturer is held in high regard and if rival suppliers are relatively unknown, the time lag for acquiring the "know-how" referred to above combined with acceptance by physicians of the particular product of the original producer may ensure that the latter will enjoy a substantial share of the market for a considerable time after the products of rival manufacturers have appeared on the market. While, therefore, abolition of patents may result in removing the opportunity for the inventor to secure royalty payments from Canada it will not necessarily mean that Canadians will make no contribution to the cost of developing new drugs. The evidence in the present inquiry suggests that drug manufacturers have secured far more from the price margins on drugs under patent control than would have been secured from any royalties which might have been awarded under compulsory licences. While it is the expectation of the Commission that the abolition of patents relating to drugs will, in time, result in reductions in the present price margins it does not consider that such margins will be so narrowed that no contribution will remain toward the costs incurred in discovering and developing new drug products.

It should also be kept in mind that discoveries in the field of medicines come from a variety of sources, of which the drug industry is only one. Some very significant discoveries of medicines have been made in Canada and the benefits of these discoveries have been secured by all countries. Future discoveries made in Canada will likewise be available to the world and in this way Canada can make its contribution to the advance of medicine. The larger the resources which are made available from public funds and private sources in Canada for research in the field of medicine the more significant and frequent are likely to be the discoveries made in Canada and consequently its contribution to the advance of medical knowledge.

As the abolition of patents relating to drugs is believed by the Commission to be the only effective remedy for the undesirable consequences arising out of the control of drugs in Canada under the patent system we recommend this course of action. In the opinion of the Commission, the abolition of patents would lead to a definite lowering of the prices of drugs hitherto protected by patents, for the patent-holding companies would have to meet much more directly the competition from the lower prices of the generic manufacturers and importers. With the safeguards for the quality of drugs which would be provided under other recommendations which the Commission has made, the medical profession and the public would have confidence in choosing between products of rival suppliers. The companies which have hitherto enjoyed patent protection might find their profits reduced for a time if there was a sudden influx into the Canadian market of drugs in large demand and which had been relatively high in price. There is no reason to believe that the established companies would not be able to live with the situation and some might consider it worthwhile to extend the range of their products and perhaps increase their over-all business. In any event, the rapid obsolescence of drugs, the importance of "know-how" in the drug manufacturing industry and the loyalty of physicians to brands familiar to them are factors which will continue to operate even if there is no patent protection. The well-regarded and progressive drug manufacturer will continue, therefore, to be in a strong position to meet competition which will arise in the absence of patents relating to drugs.

11. Summary of Recommendations

1. There should be more stringent regulations under the Food and Drugs Act with respect to the manufacture, promotion and introduction of drugs, in order to give reasonable assurance that all prescription drugs offered for sale in Canada are safe to use and of good quality.

2. The staff of the Food and Drug Directorate should be enlarged considerably to ensure thorough enforcement of the regulations.

3. In the opinion of the Commission, the following changes should be made in the Food and Drug Regulations:

- (a) All premises in which drugs are manufactured should be subject to inspection by the Food and Drug Directorate.
- (b) Requirements in connection with new drug submissions should be extended to include detailed reports of the tests made to establish the therapeutic effectiveness of the drug as well as the present requirement of reports of tests to establish the safety of the drug. Such a change would make mandatory a joint evaluation of toxicity and efficacy before a new drug is put on sale.
- (c) The Food and Drug Directorate should be given the duty of inspecting and assaying samples from a sufficiently large number of batches of every prescription drug manufactured in Canada or imported from abroad to make it reasonably certain that it meets minimum standards of purity and therapeutic efficacy.
- (d) All labels, advertisements or other descriptive material relating to single drugs and official compounds should be required to carry the proper name prominently and in type at least as large as that used for the brand name. A study should be made to ascertain if and to what extent a similar requirement would be feasible in respect of compound ethical drugs.

4. Consideration should be given to the advisability of bringing under the supervision of the Food and Drug Directorate all advertising and promotion activities related to drugs, including the distribution of samples and the content of advertising literature.

5. Consideration should be given to the establishment, under the auspices of the federal government, of an authoritative publication giving all necessary particulars concerning new drugs.

6. The compulsory licence provision of the Patent Act with respect to drugs has been used infrequently and in the opinion of the Commission cannot be relied upon to achieve the purpose intended by Parliament of ensuring that medicines should be available to the public

at the lowest possible price consistent with giving to the inventor due reward for the research leading to the invention. The Commission has considered whether such an objective would be assured if compulsory licences under section 41(3) of the Patent Act were made issuable as of right and has concluded that such a change would make no appreciable difference in the present situation. As the Commission believes that close control exercised by patents has made it possible to maintain prices of certain drugs at levels higher than would have obtained otherwise and that such patent control has produced no benefits to the public of Canada which would outweigh the disadvantages of the monopoly, the Commission recommends that patents with respect to drugs be abolished. In the opinion of the Commission this is the only effective remedy to reduce the price of drugs in Canada.

7. The retail pharmacists' practice of coding prescriptions to indicate the price charged or quoted should be abandoned and consideration should be given by pharmaceutical associations to removing from their rules any provisions in any way related to the practice.

(Sgd.) Pierre Carignan
Member

Ottawa
January 24, 1963.

APPENDIX A

COMBINES INVESTIGATION ACT

"28. All inquiries under this Act shall be conducted in private, except that the Chairman of the Commission may order that all or any portion of any proceedings before the Commission or any member thereof shall be conducted in public.

. . .

30. In any case where use has been made of the exclusive rights and privileges conferred by one or more patents for invention or by one or more trade marks so as

- (a) unduly to limit the facilities for transporting, producing, manufacturing, supplying, storing or dealing in any article or commodity which may be a subject of trade or commerce; or
- (b) unduly to restrain or injure trade or commerce in relation to any such article or commodity; or
- (c) unduly to prevent, limit or lessen the manufacture or production of any such article or commodity or unreasonably to enhance the price thereof; or
- (d) unduly to prevent or lessen competition in the production, manufacture, purchase, barter, sale, transportation or supply of any such article or commodity;

the Exchequer Court of Canada, on an information exhibited by the Attorney General of Canada, may for the purpose of preventing any use in the manner defined above of the exclusive rights and privileges conferred by any patents or trade marks relating to or affecting the manufacture, use or sale of such article or commodity, make one or more of the following orders:

- (i) declaring void, in whole or in part, any agreement, arrangement or licence relating to such use;

- (ii) restraining any person from carrying out or exercising any or all of the terms or provisions of such agreement, arrangement or licence;
- (iii) directing the grant of licences under any such patent to such persons and on such terms and conditions as the court may deem proper, or, if such grant and other remedies under this section would appear insufficient to prevent such use, revoking such patent;
- (iv) directing that the registration of a trade mark in the register of trade marks be expunged or amended; and
- (v) directing that such other acts be done or omitted as the Court may deem necessary to prevent any such use;

but no order shall be made under this section which is at variance with any treaty, convention, arrangement or engagement respecting patents or trade marks with any other country to which Canada is a party."

APPENDIX B

FOOD AND DRUGS ACT

"3. (1) No person shall advertise any food, drug, cosmetic or device to the general public as a treatment, preventative or cure for any of the diseases, disorders or abnormal physical states mentioned in Schedule A.

(2) No person shall sell any food, drug, cosmetic or device

(a) that is represented by label, or

(b) that he advertises to the general public as a treatment, preventative or cure for any of the diseases, disorders or abnormal physical states mentioned in Schedule A.

. . .

8. No person shall sell any drug that

(a) was manufactured, prepared, preserved, packed or stored under unsanitary conditions; or

(b) is adulterated.

9. (1) No person shall label, package, treat, process, sell or advertise any drug in a manner that is false, misleading, or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety.

(2) A drug that is not labelled or packaged as required by the regulations, or is labelled or packaged contrary to the regulations, shall be deemed to be labelled or packaged contrary to subsection (1).

10. (1) Where a standard has been prescribed for a drug, no person shall label, package, sell or advertise any substance in such a manner that it is likely to be mistaken for such drug, unless the substance complies with the prescribed standard.

(2) Where a standard has not been prescribed for a drug, but a standard for the drug is contained in any publication mentioned in Schedule B, no person shall label, package,

sell or advertise any substance in such a manner that it is likely to be mistaken for such drug, unless the substance complies with such standard.

(3) Where a standard for a drug has not been prescribed and no standard for the drug is contained in any publication mentioned in Schedule B, no person shall sell such drug, unless

- (a) it is in accordance with the professed standard under which it is sold, and
- (b) it does not resemble, in a manner likely to deceive, any drug for which a standard has been prescribed or is contained in any publication mentioned in Schedule B.

11. No person shall manufacture, prepare, preserve, package or store for sale any drug under unsanitary conditions.

12. No person shall sell any drug described in Schedule C or D unless the Minister has, in prescribed form and manner, indicated that the premises in which the drug was manufactured and the process and conditions of manufacture therein are suitable to ensure that the drug will not be unsafe for use.

13. No person shall sell any drug described in Schedule E unless the Minister has, in prescribed form and manner, indicated that the batch from which the drug was taken is not unsafe for use.

14. (1) No person shall distribute or cause to be distributed any drug as a sample.

(2) Subsection (1) does not apply to the distribution, under prescribed conditions, of samples of drugs to physicians, dentists, veterinary surgeons or pharmacists.

14A. No person shall sell any drug described in Schedule H.

. . .

21. (1) An inspector may at any reasonable time

- (a) enter any place where on reasonable grounds he believes any article to which this Act or the regulations apply is manufactured,

prepared, preserved, packaged or stored, examine any such article and take samples thereof, and examine anything that he reasonably believes is used or capable of being used for such manufacture, preparation, preservation, packaging or storing;

- (b) open and examine any receptacle or package that on reasonable grounds he believes contains any article to which this Act or the regulations apply;
- (c) examine any books, documents or other records found in any place mentioned in paragraph (a) that on reasonable grounds he believes contain any information relevant to the enforcement of this Act with respect to any article to which this Act or the regulations apply and make copies thereof or extracts therefrom; and
- (d) seize and detain for such time as may be necessary any article by means of or in relation to which he reasonably believes any provision of this Act or the regulations have been violated.

(2) For the purposes of subsection (1), the expression 'article to which this Act or the regulations apply' includes

- (a) any food, drug, cosmetic or device,
- (b) anything used for the manufacture, preparation, preservation, packaging or storing thereof, and
- (c) any labelling or advertising material.

(3) An inspector shall be furnished with a prescribed certificate of designation and on entering any place pursuant to subsection (1) shall if so required produce the certificate to the person in charge thereof.

(4) The owner or person in charge of a place entered by an inspector pursuant to subsection (1) and every person found therein shall give the inspector all reasonable assistance in his power and furnish him with such information as he may reasonably require.

(5) No person shall obstruct an inspector in the carrying out of his duties under this Act or the regulations.

(6) No person shall knowingly make any false or misleading statement either verbally or in writing to any inspector engaged in carrying out his duties under this Act or the regulations.

(7) No person shall remove, alter or interfere in any way with any article seized under this Act without the authority of an inspector.

(8) Any article seized under this Act may at the option of an inspector be kept or stored in the building or place where it was seized or may at the direction of an inspector be removed to any other proper place.

. . .

24. (1) The Governor in Council may make regulations for carrying the purposes and provisions of this Act into effect, and, in particular, but not so as to restrict the generality of the foregoing, may make regulations

. . .

(n) respecting the distribution or the conditions of distribution of samples of any drug; and

(o) respecting

(i) the method of preparation, manufacture, preserving, packing, labelling, storing and testing of any new drug, and

(ii) the sale or the conditions of sale of any new drug, and defining for the purposes of this Act the expression 'new drug'.

. . .

SCHEDULE A

Alcoholism
Appendicitis
Arteriosclerosis
Blood Poisoning
Bright's Disease
Cancer
Diabetes
Diphtheria
Disorders of menstrual flow
Disorders of the prostatic gland
Dropsy
Epilepsy
Erysipelas
Gallstones, Kidney Stones, Bladder Stones
Gangrene
Goitre
Heart Diseases
High Blood Pressure
Infantile Paralysis
Influenza
Lockjaw
Locomotor Ataxia
Obesity
Pleurisy
Pneumonia
Ruptures
Scarlet Fever
Sexual Impotence
Small Pox
Spinal Meningitis
Trachoma
Tuberculosis
Tumours
Typhoid Fever
Ulcers of the gastro-intestinal tract
Venereal Diseases

SCHEDULE B

Name	Abbreviation	Edition
Pharmacopoea Internationalis	(Ph.I)	I
The British Pharmacopoeia	(B.P.)	1958
The Pharmacopoeia of the United States of America	(U.S.P.)	XVI
Codex Français	(Codex)	VII
The Canadian Formulary	(C.F.)	1949
The British Pharmaceutical Codex	(B.P.C.)	1959
The National Formulary	(N.F.)	XI

SCHEDULE C

Liver extract injectable
Liver extract injectable with other medication
Liver extract injectable crude
Liver extract injectable crude with other medication
Insulin
Insulin made from zinc-insulin crystals
Globin insulin with zinc
Insulin zinc suspension
N.P.H. Insulin, Isophane Insulin
Protamine zinc insulin
Anterior pituitary extracts
Radioactive Isotopes

SCHEDULE D

Living vaccines for oral or parenteral use
Drugs prepared from micro-organisms or viruses
for parenteral use
Sera and drugs analogous thereto for parenteral use
Antibiotics for parenteral use

SCHEDULE E

Arsphenamine
Dichlorophenarsine Hydrochloride
Neoarsphenamine
Oxophenarsine Hydrochloride
Sensitivity Discs and Tablets
Sulpharsphenamine

SCHEDULE F

Part I

Item
No.

- A.1 Amitriptyline and its salts
- B.2 Bemegride
- B.3 Bromal and the following derivatives:
 - (a) bromal hydrate
 - (b) brometone
 - (c) bromoform
- C.1 Carbromal and the following derivatives:
 - (a) acetylcarbromal
 - (b) allylisopropylacetylurea
 - (c) bromisoval
 - (d) diethylbromacetamide

- C.2 Chloral and the following derivatives:
 - (a) alpha-chloralose
 - (b) butyl chloral hydrate
 - (c) chloralformamide
 - (d) chloral hydrate (except in preparations for external use containing not more than 1 per cent)
 - (e) chloralimide
- C.3 Chlordiazepoxide and its salts
- D.1 Diazepam and its salts [P.C. 1962-1234]
- D.2 Diethylpropion and its salts [P.C. 1962-1470]
- E.1 Ethchlorvynol
- E.2 Ethinamate
- E.3 Ethyl Trichloramate
- E.4 Etryptamine and its salts
- G.1 Glutethimide
- H.1 Hexacyclonate sodium
- I.1 Imipramine and its salts
- I.2 Iproniazid and its salts
- I.3 Isocarboxazid and its salts
- M.1 Mescaline and its salts
- M.2 Metaldehyde
- M.3 Methaqualone and its salts
- M.5 Methylparafynol
- M.6 Methylphenidate and its salts
- M.7 Methyprylon
- N.1 Nialamide and its salts
- P.1 Paraldehyde
- P.2 Phendimetrazine and its salts
- P.3 Phenelzine and its salts
- P.4 Pheniprazine and its salts
- P.5 Phenmetrazine and its salt
- P.6 Pipradrol and its salts
- S.1 Sulphonal and alkyl sulphonals
- T.1 Thalidomide

Part II

Item
No.

- A.1 Aconiazide and its salts
- A.2 Adrenocortical hormones and their salts and derivatives
- A.3 Aminoglutethimide
- A.4 4-amino-N-methylpteroyl glutamic acid and its salts
- A.5 Aminopterin and its salts
- A.6 4-amino-pteroyl aspartic acid and its salts
- A.7 Aminopyrine and its derivatives
- A.8 Antibiotics, the following and their salts and derivatives:

- (a) Carbomycin
- (b) Chloramphenicol
- (c) Cycloserine
- (d) Dihydrostreptomycin
- (e) Erythromycin
- (f) Griseofulvin
- (g) Kanamycin
- (h) Novobiocin
- (i) Oleandomycin
- (j) Penicillin (excluding lozenges that contain not more than 3, 000 International Units per dose)
- (k) Polymyxin B (except for topical use or for local action in the oral cavity or nasal passages)
- (l) Spiramycin
- (m) Streptomycin
- (n) Tetracycline
- (o) Viomycin
- A. 9 Anticoagulants, the following:
 - (a) Bishydroxycoumarin and its salts and derivatives
 - (b) 4-hydroxycoumarin and its derivatives when sold or recommended as anticoagulants
 - (c) Phenylindanedione and its derivatives
- B. 1 Busulfan
- C. 1 Calcium Carbimide
- C. 2 Chlorambucil and its salts and derivatives
- C. 3 Chlormezanone
- C. 4 Chlorprothixene and its salts
- C. 5 Cinchophen and its salts
- D. 1 Diphenylmethane derivatives, the following and their salts:
 - (a) Azacyclonol
 - (b) Benactyzine
 - (c) Captodiamine
 - (d) Hydroxyzine
 - (e) Piperliate
- D. 2 2,4-dinitrophenol and its salts and derivatives
- D. 3 Disulfiram
- E. 1 Ectylurea and its salts
- E. 2 Emylcamate
- E. 3 Ergot alkaloids and their salts
- E. 4 Ethionamide and its salts
- F. 1 Fluorouracil [P.C. 1962-1654]
- H. 1 Hydantoin derivatives and their salts (except in preparations for external use only)
- I. 1 Isoniazid
- L. 1 Liothyronine
- M. 1 Meclizine [P.C. 1962-1719]
- M. 2 Mephenoxalone
- M. 3 Meprobamate
- M. 4 6-mercaptopurine
- M. 5 Methopyrapone and its salts
- M. 6 Methysergide and its salts and derivatives [P.C. 1962-1234]
- N. 1 Neocinchophen and its salts

- Item
No.
- O.1 Oil of Apiol
 - O.2 Oxanamide
 - O.3 Oxyphenbutazone and its salts
 - P.1 Paramethadione
 - P.2 Phenacemide
 - P.3 Phenaglycodol
 - P.4 Phenformin and its salts
 - P.5 Phenothiazine derivatives, the following and their salts:
 - (a) Acepromazine
 - (b) Chlorpromazine
 - (c) Fluphenazine
 - (d) Levomepromazine
 - (e) Mepazine
 - (f) Perphenazine
 - (g) Phenthoxate
 - (h) Prochlorperazine
 - (i) Promazine
 - (j) Thiopropazate
 - (k) Thioproperazine [P.C. 1962-1234]
 - (l) Thioridazine
 - (m) Trifluoperazine
 - (n) Triflupromazine
 - (o) Trimeprazine
 - P.6 Phenylbutazone and its salts
 - P.7 Primidone
 - P.8 Prothipendyl Hydrochloride
 - P.9 Pyrazinamide
 - R.1 Rauwolfia and the following Rauwolfia alkaloids and their salts:
 - (a) Deserpidine
 - (b) Raubasine
 - (c) Rescinamine
 - (d) Reserpine
 - S.1 Sex hormones (except cosmetic preparations containing sex hormones, which are demonstrated to be free from systemic effects)
 - S.2 Succinimide and its salts and derivatives (except those compounds used for decontaminating water)
 - S.3 Sulfinpyrazone and its salts
 - S.4 Sulphonamides and their salts and derivatives
 - T.1 Thiouracil and its derivatives
 - T.2 Thyroid
 - T.3 Thyroxin and its salts
 - T.4 Tolbutamide and its salts and derivatives
 - T.5 Tranlycypromine
 - T.6 Tretamine
 - T.7 Triiodothyropropionic acid
 - T.8 Trimethadione

SCHEDULE G

Item
No.

1. Amphetamine and its salts
2. Barbituric acid and its salts and derivatives
3. Benzphetamine and its salts [P.C. 1962-1471]
4. Methamphetamine and its salts

SCHEDULE H

Thalidomide
Lysergic acid diethylamide"

APPENDIX C

FOOD AND DRUG REGULATIONS

"C.01.001. In this Part,

. . . .

- (b) 'common name' means, with reference to a drug, the name in English or French by which the drug is commonly known,

. . . .

- (e) 'official drug' means any drug
- (i) for which a standard is provided in these Regulations, or
 - (ii) for which no standard is provided in these Regulations but for which a standard is provided in any of the publications mentioned in SCHEDULE B to the Act,

. . . .

- (j) 'proper name' means, with reference to a drug, the name in English or French
- (i) assigned to the drug in section C.01.002,
 - (ii) that appears in bold-face type for the drug in these Regulations and, where the drug is dispensed in a form other than that described in this Part the name of the dispensing form,
 - (iii) specified in the Canadian licence^[1] in the case of drugs included in SCHEDULE C or SCHEDULE D to the Act, or
 - (iv) assigned in any of the publications mentioned in SCHEDULE B to the Act in the case of drugs not included in subparagraphs (i), (ii) or (iii) of this paragraph, and

. . . .

[1] See C.03.001(b) and C.04.001(c).

C.01.004 Except as provided in these regulations the label of a drug shall carry

- (a) on the main panel of both the inner and the outer labels
 - (i) the proper name and the standard under which the drug was manufactured which shall, if the standard is contained in any publication mentioned in SCHEDULE B to the ACT, be stated in full or by the abbreviation therein provided, or if the standard is provided by Division 5 or Division 6 of Part C of these regulations, the standard shall be designated as Canadian Standard Drug or C.S.D. or, if the drug is manufactured under Canadian licence^[1] it shall be sufficient to state the Canadian licence number, and where there is a proprietary or brand name the proper name shall immediately precede or follow the said proprietary or brand name in type of not less than one-half the size thereof, or
 - (ii) if there is no proper name^[2], the common name^[3],
- (b) on both the inner and the outer labels
 - (i) the name of the manufacturer or distributor of the drug,
 - (ii) the address of the manufacturer or distributor, except that where the immediate container contains 5 millilitres or less, this statement need not be made on the inner label,
 - (iii) where a drug is intended for internal or parenteral use, the lot number^[4] thereof,

[1] See C.03.001(b) and C.04.001(e).

[2] See C.01.001(j).

[3] See C.01.001(b).

[4] The lot number should be preceded by the words "Lot Number" or by "Lot No.", "Lot", or "(L)".

- (iv) adequate directions for use,
- (v) the proper or if there is no proper name the common name of each medicinal ingredient contained therein except upon
 - (1) shipping cases or wrapping material,
 - (2) official drugs^[1]
 - (3) drugs sold on prescription, or
 - (4) medicines registered under the Proprietary or Patent Medicine Act, and

(c) on the outer label

- (i) a correct statement of net contents in terms of weight, measure, or number, and
- (ii) where the drug is intended for parenteral use, the name and proportion of any preservative present therein.

. . .

C.01.027. No person shall advertise to the general public for human use, a drug that carries a recommended single or daily dosage or a statement of concentration in excess of the limits provided by C.01.021.

. . .

C.01.041. No person shall sell a drug listed or described in SCHEDULE F to the Act in these regulations referred to as SCHEDULE F Drug unless he has received a prescription therefor, and such prescription shall

- (a) if in writing, be retained by the dispenser thereof for a period of at least two years from the date of filling,
- (b) if verbally given, forthwith be reduced to writing, retained by the dispenser thereof for a period of at least two years and shall show

[1] See C.01.001(e).

- (i) the date and number of the prescription,
- (ii) the name and address of the person named therein,
- (iii) the name and quantity of the drug specified therein,
- (iv) the names of the persons issuing and receiving the prescription, and
- (v) the direction for use given therewith, including whether or not the practitioner directs the refilling of the prescription.

. . .

C.01.044. No person shall advertise to the general public for human use a SCHEDULE F Drug.

. . .

C.01.301. 'New drug' means a drug that because of its

- (a) composition,
- (b) method of manufacture,
- (c) dosage, or
- (d) route of administration

is not generally recognized by persons qualified to evaluate the safety of the drug as safe for the use for which it is proposed or recommended and includes a drug for which a new drug submission has been filed in accordance with section C.01.302 or C.01.304 but the safety of which has not been established by use for a material time or to a material extent.

C.01.302. Subject to section C.01.305, no person shall sell a new drug unless the manufacturer thereof has filed with the Minister, in form, manner and content satisfactory to the Minister, a new drug submission, in duplicate, that includes

- (a) a description of the drug and a declaration of the proper name^[1], if any, or if it has no proper name, the name under which it is proposed to be sold;

[1] See C.01.001(j).

- (b) a statement of all the ingredients, the route of administration, the proposed dosage, the claims to be made for such drug and a description of the pharmaceutical forms in which it is proposed to be sold;
- (c) details of the method of manufacture;
- (d) detailed reports of the tests made to establish the safety of the drug for the purpose and under the conditions of use recommended;
- (e) details of the tests applied to control the potency, purity and safety of the drug;
- (f) a draft of every label proposed to be used;
- (g) samples of the drug in the finished pharmaceutical form in which it is proposed to be sold; and
- (h) samples of the components thereof as the Minister may require.

C.01.303. Subject to section C.01.305, no person shall sell a new drug in respect of which a new drug submission has been filed with the Minister if a material change has been made in the

- (a) conditions of use, including the indications for use and the route of administration,
- (b) labelling,
- (c) pharmaceutical form,
- (d) dosage,
- (e) strength, quality or purity, or
- (f) manufacturing methods or facilities for control, unless the manufacturer has filed with the Minister a supplement to the new drug submission, that is satisfactory to the Minister, describing the change and giving all particulars respecting the safety of the drug under the revised conditions described therein.

C.01.304. Where a notice of compliance has been issued to a manufacturer in accordance with section C.01.305, another manufacturer may, in lieu of filing a new drug submission, provide the Minister with a submission that includes

- (a) the information referred to in paragraphs (a) to (c) and (e) to (h) of section C.01.302; and

- (b) detailed reports, satisfactory to the Minister, of tests carried out to establish the safety of the drug under the conditions of use recommended.
- C.01.305. The Minister shall, within ninety days after the filing of a new drug submission, a supplement thereto or a submission referred to in section C.01.304, notify the person filing the submission or supplement whether the data and information submitted comply with the requirements of section C.01.302, C.01.303 or C.01.304, as the case may be, and upon notice of compliance the drug may be sold subject to the provisions of the Food and Drugs Act and these Regulations.
- C.01.306. No person shall sell a new drug unless that drug has been manufactured by a manufacturer to whom a notice of compliance has been issued in accordance with section C.01.305.
- C.01.307. Notwithstanding sections C.01.302, C.01.303 and C.01.304, a new drug may be sold to investigators qualified to use such drug for the sole purpose of obtaining clinical and scientific data with respect to its safety, stability, dosage or efficacy, if
- (a) the Minister is first informed of the identifying name or mark by which the drug can be recognized;
 - (b) both the inner and outer labels on the packages of such drug carry the statement 'To Be Used By Qualified Investigators Only';
 - (c) the manufacturer, prior to making a shipment of the drug, ensures that any person to whom the drug is sold is a qualified investigator and has the facilities for the investigation to be conducted by him and that the drug will be used solely by him or under his direction for the investigation; and
 - (d) the manufacturer keeps accurate records of such distribution and of the results of such investigation and makes those records available for inspection on the request of the Director.

. . .

C.03.001. In this Division

. . .

- (b) 'licence' or 'Canadian licence' means the prescribed form and manner used by the Minister to indicate that the premises in which a drug was in whole or in part manufactured, and the process and conditions of manufacture therein are suitable to ensure that the drug is not unsafe for use,

. . .

C.04.001. In this Division

. . .

- (c) 'licence' or 'Canadian licence' means the prescribed form and manner used by the Minister to indicate that the premises in which a drug was in whole or in part manufactured, and the process and conditions of manufacture therein are suitable to ensure that the drug is not unsafe for use, and

. . .

C.04.006 As a condition of the issuance and continuation of a licence^[1], the Minister may require a manufacturer who manufactures a drug outside Canada under a Canadian licence

- (a) to designate a representative in Canada,
- (b) to furnish the name and address of such representative who shall maintain satisfactory records of the distribution of the drug in Canada.

C.04.007. A licence^[1] shall be in the form prescribed therefor in Appendix III and shall expire on the 31st of March of each year."

[1] See C.04.001(c).

APPENDIX D

TRADE MARKS ACT

"2. In this Act,

. . .

- (u) 'trade name' means the name under which any business is carried on, whether or not it is the name of a corporation, a partnership or an individual;

. . .

12. (1) Subject to section 13, a trade mark is registrable if it is not

- (a) a word that is primarily merely the name or the surname of an individual who is living or has died within the preceding thirty years;
- (b) whether depicted, written or sounded, either clearly descriptive or deceptively misdescriptive in the English or French languages of the character or quality of the wares or services in association with which it is used or proposed to be used or of the conditions of or the persons employed in their production or of their place of origin;
- (c) the name in any language of any of the wares or services in connection with which it is used or proposed to be used;
- (d) confusing with a registered trade mark; or
- (e) a mark of which the adoption is prohibited by section 9 or 10.

(2) A trade mark that is not registrable by reason of paragraph (a) or (b) of subsection (1) is registrable if it has been so used in Canada by the applicant or his predecessor in title as to have become distinctive at the date of filing an application for its registration."

APPENDIX E

PATENT ACT

41. (1) In the case of inventions relating to substances prepared or produced by chemical processes and intended for food or medicine, the specifications shall not include claims for the substance itself, except when prepared or produced by the methods or processes of manufacture particularly described and claimed or by their obvious chemical equivalents.

(2) In an action for infringement of a patent where the invention relates to the production of a new substance, any substance of the same chemical composition and constitution shall, in the absence of proof to the contrary, be deemed to have been produced by the patented process.

(3) In the case of any patent for an invention intended for or capable of being used for the preparation or production of food or medicine, the Commissioner shall, unless he sees good reason to the contrary, grant to any person applying for the same, a licence limited to the use of the invention for the purposes of the preparation or production of food or medicine but not otherwise; and, in settling the terms of such licence and fixing the amount of royalty or other consideration payable [;] the Commissioner shall have regard to the desirability of making the food or medicine available to the public at the lowest possible price consistent with giving to the inventor due reward for the research leading to the invention.

(4) Any decision of the Commissioner under this section is subject to appeal to the Exchequer Court.

(5) This section applies only to patents granted after the 13th day of June, 1923.

. . ."

APPENDIX F

PROPRIETARY OR PATENT MEDICINE ACT

"2. (1) In this Act

. . .

(d) 'proprietary or patent medicine' means every artificial remedy or prescription manufactured for the internal or external use of man, the name, composition or definition of which is not to be found in the British Pharmacopoeia, the Codex Medicamentarius of France, the Pharmacopoeia of the United States, or any foreign pharmacopoeia approved by the Minister, the Canadian Formulary, the National Formulary of the United States of America, or any formulary adopted by any properly constituted pharmaceutical association representing Canada and approved by the Minister; or upon which is not printed in a conspicuous manner the true formula or list of medicinal ingredients contained in it.

. . .

7. The manufacture, importation or sale of all proprietary or patent medicines containing opium or its derivatives for internal use are prohibited.

8. (1) No proprietary or patent medicine shall be manufactured, imported, exposed or offered for sale or sold in Canada, if

- (a) it contains cocaine or any of its salts or preparations;
- (b) it contains alcohol in excess of the amount required as a solvent or preservative, or is not sufficiently medicated to make it unfit for use as a beverage;
- (c) it contains any drug that is included in the Schedule the name of which and the amount per dose of which are not conspicuously printed on an inseparable part of the label and wrapper of the bottle, box or other container, or if the quantity of such drug exceeds the amount permitted by the Advisory Board;

- (d) it contains any drug that is included in the Schedule and the name of such drug as used on the label is not the commonly employed name of such drug;
- (e) the article is represented as a cure for any disease; or
- (f) any false, misleading or exaggerated claims are made on the wrapper or label, or in any advertisement of the article.

(2) No proprietary or patent medicine intended for administration to infants under one year of age shall contain any derivative of coal-tar that, in the opinion of the Advisory Board, is dangerous to children under one year of age."

APPENDIX G

SCHEDULE A OF THE CUSTOMS TARIFF

"Tariff Item	Goods Subject to Duty and Free Goods	British Prefer- ential Tariff	Most- Favoured- Nation Tariff	General Tariff	Effective Date No. of Memo
	. . .				
220a	Chemical preparations, com- pounded of more than one sub- stance, n.o.p.:-				
	(i) When dry, or liquid con- taining not more than two and one-half per centum of proof spirit.....	15 p.c.	25 p.c.	25 p.c.	27/6/44, D47-173
	GATT		20 p.c.		1/1/48, D48-28&S
	GATT				
Ex.	Hydrolized animal matter for use as retarder for calcined gypsum		10 p.c.		30/6/56, D48-28-3
	(ii) All others.....	30 p.c.	30 p.c.	30 p.c.	27/6/44, D47-173
	GATT		25 p.c.		1/1/48, D48-28&S
	Any article in this item con- taining more than forty per cent of proof spirit shall be rated for duty at.....per gallon	\$3.00	\$3.00	\$3.00	
	and 30 p.c.		30 p.c.	30 p.c.	27/6/44, D47-173
	GATTper gallon		\$2.00		6/6/51, D48-28-1
	and		20 p.c.		18
	. . . "				

APPENDIX H

EXCISE TAX ACT

"30. (1) There shall be imposed, levied and collected a consumption or sales tax of eight per cent on the sale price of all goods

- (a) produced or manufactured in Canada
 - (i) payable, in any case other than a case mentioned in subparagraph (ii), by the producer or manufacturer at the time when the goods are delivered to the purchaser or at the time when the property in the goods passes, whichever is the earlier, and
 - (ii) payable, in a case where the contract for the sale of the goods (including a hire-purchase contract and any other contract under which property in the goods passes upon satisfaction of a condition) provides that the sale price or other consideration shall be paid to the manufacturer or producer by instalments (whether the contract provides that the goods are to be delivered or property in the goods is to pass before or after payment of any or all instalments), by the producer or manufacturer pro tanto at the time each of the instalments becomes payable in accordance with the terms of the contract;
- (b) imported into Canada, payable by the importer or transferee who takes the goods out of bond for consumption at the time when the goods are imported or taken out of warehouse for consumption;
- (c) sold by a licensed wholesaler, payable by him at the time of delivery to the purchaser, and the tax shall be computed
 - (i) on the duty paid value of goods, if they were imported by the licensed wholesaler, or

- (ii) on the price for which the goods were purchased by the licensed wholesaler, if they were not imported by him, and such price shall include the amount of the excise duties on goods sold in bond; or
- (d) retained by a licensed wholesaler for his own use or for rental by him to others, payable by the licensed wholesaler at the time the goods are put to his own use or first rented to others, and the said tax shall be computed
 - (i) on the duty paid value of the goods, if they were imported by the licensed wholesaler, or
 - (ii) on the price for which the goods were purchased by the licensed wholesaler, if they were not imported by him, and such price shall include the amount of the excise duties on goods sold in bond.

(2) Notwithstanding anything in subsection (1), the consumption or sales tax shall not be payable on goods

- (a) sold by a licensed manufacturer to another licensed manufacturer if the goods are partly manufactured goods;
- (b) imported by a licensed manufacturer if the goods are partly manufactured goods;
- (c) imported by a licensed wholesaler otherwise than for his own use or for rental to others, on importation;
- (d) sold by a licensed manufacturer to a licensed wholesaler otherwise than for his own use or for rental to others;
- (e) sold by a licensed wholesaler to a licensed manufacturer if the goods are partly manufactured goods; or
- (f) sold by a licensed wholesaler to another licensed wholesaler, but if a licensed wholesaler sells goods to another licensed wholesaler at a price less than the value upon which the tax would be computed under paragraph (c)

of subsection (1), the vendor forthwith becomes liable to pay the tax upon the difference between such value and his sale price.

(3) In case any person other than the manufacturer or producer or importer or transferee or licensed wholesaler or jobber hereinbefore mentioned acquires from or against any one of these persons the right to sell any goods, whether as a result of the operation of law or of any transaction not taxable under this section, the sale of such goods by him shall be taxable as if made by the manufacturer or producer or importer or transferee or licensed wholesaler or jobber as the case may be and the person so selling is liable to pay the tax.

. . .

32. (1) The tax imposed by section 30 does not apply to the sale or importation of the articles mentioned in Schedule III.

. . .

Schedule III

. . .

CHARITABLE, HEALTH, ETC.

Adrenocorticotrophin (ACTH); Cortisone; Insulin; Radium;

Articles and materials for the sole use of any bona fide public hospital certified to be such by the Department of National Health and Welfare, when purchased in good faith for use exclusively by the said hospital and not for resale;

. . .

Liver extract for use exclusively in the treatment of anaemia;

. . .

Vaccine for use in the prevention of poliomyelitis, and material for use exclusively in the manufacture thereof;

. . ."

APPENDIX I

OLD AGE SECURITY ACT

"10. (1) There shall be imposed, levied and collected an Old Age Security tax of three per cent on the sale price of all goods in respect of which tax is payable under section 30 of the Excise Tax Act, at the same time, by the same persons and subject to the same conditions as the tax payable under that section.

(2) Subsection (1) shall be read and construed as though the tax imposed thereby were imposed by section 30 of the Excise Tax Act; and all the provisions of the Excise Tax Act shall be read and construed as though the tax imposed by subsection (1) were an addition to the tax imposed by the provisions of the said section 30.

. . ."

APPENDIX J

RADIO (TV) BROADCASTING REGULATIONS UNDER THE BROADCASTING ACT⁽¹⁾

"FOOD AND DRUGS: PROPRIETARY OR PATENT MEDICINES

11. (1) No station or network operator shall broadcast any advertisement or testimonial for any article to which the Proprietary or Patent Medicine Act or the Food and Drugs Act applies unless the continuity of the advertisement or testimonial has been approved by the Department of National Health and Welfare and by a representative of the Board and bears the registration number assigned by the Board.

(2) No station or network operator shall broadcast any recommendation for the prevention, treatment or cure of a disease or ailment unless the continuity thereof has been approved by the Department of National Health and Welfare and by a representative of the Board and bears the registration number assigned by the Board.

(3) Continuities submitted for approval pursuant to this Regulation shall be forwarded to the Board in triplicate at least two weeks in advance of intended use.

(3a) Every station and network operator shall maintain and produce to a representative of the Board, upon request, a record of each continuity approved under subsection (1) or (2) and broadcast by the station or network operator which record shall contain:

- (a) the name of the product,
- (b) the name of the advertiser or advertising agency submitting the continuity, and
- (c) the registration number assigned to the continuity by the Board.

(4) Inspectors of the Food and Drugs Division, Department of National Health and Welfare, are authorized to act as representatives of the Board for the purposes of the enforcement of this section."

(1) The Canada Gazette, Part II, Vol. 93, No. 23, December 9, 1959, p. 1198; Vol. 94, No. 20, October 26, 1960, p. 1355; Vol. 96, No. 10, May 23, 1962, p. 576.

APPENDIX K

"Comprehensive Medical Care Study Committee [1]"

We have received from the Comprehensive Medical Care Study Committee the first of a series of reports on drug costs, the present one dealing with asthma. This speaks for itself, and bears out the fact that except for steroids the cost of the drugs usually used in asthma is not excessive.

A point that should be made is that there are on the market several therapeutic combinations of drugs, e.g., Aminophyllin, Ephedrine and Amobarbital, or Theophylline, Ephedrine and Phenobarb, and the like. These combinations, put out by various pharmaceutical houses, may not exceed the total cost of the component parts by an excessive amount, and the increased cost may be justified by the simplicity of the Trade Name prescription and the convenience to the patient. On the other hand certain Trade Name combinations, in particular those containing steroids, are very expensive and should not be prescribed without taking the cost factor into serious consideration.

SOME RELATIVE COSTS OF THE ORAL DRUG TREATMENT OF ASTHMA

Useful Drugs:

Bronchodilators:

Ephedrine -- the mainstay of the oral drug treatment of most cases of asthma. Unwanted side effects include insomnia, palpitations, gastric irritation.

Aminophylline -- an effective drug when given I-V or by rectal suppository, but gastric irritation prevents effective oral dosage.

Inhalants by nebulization --adrenalin and isoproteremol (not further considered here.)

Adrenocortical hormones:

The occasionally serious side effects preclude the use of these drugs except in resistant cases.

Antihistamines:

Ineffective except in the unusual case of histamine mediated hypersensitivity asthma.

[1] Reproduced from the British Columbia Medical Journal, Vol.2, No.8, August 1960, pp.507-508.

Costs of oral medication (according to suggested retail price):

Ephedrine	gr. $\frac{1}{2}$	100 tablets	2.75
Amobarbital	grs. $1\frac{1}{2}$	30 tablets	2.25
Phenobarbitone	gr. $\frac{1}{2}$	100 tablets	1.50
Aminophylline	grs. $1\frac{1}{2}$	100 tablets	3.75
Prednisone	mgm. 5	100 tablets	14.00

Cost of one month's therapy with:

Ephedrine gr. $\frac{1}{2}$ t.i.d. and amobarbital gr. $1\frac{1}{2}$ h.s.	5.00
Ephedrine gr. $\frac{1}{2}$ t.i.d. and phenobarbitone gr. $\frac{1}{2}$ t.i.d.	4.25

Two popular Trade Name combinations of drugs are:

- A. Aminophylline gr. 2 Ephedrine gr. $\frac{3}{8}$ Amobarbital gr. $\frac{3}{8}$
- B. Theophylline gr. 2 Ephedrine gr. $\frac{3}{8}$ Phenobarbitone gr. $\frac{1}{8}$

Cost of one month's therapy with:

A.	--- tabs. 1 t.i.d.	\$7.95
B.	--- tabs. 1 t.i.d.	7.00

Two other Trade Name combinations of drugs advertised as treatment of asthma are:

- C. Prednisolone mgm. 5 Hydroscyzine Hydrochloride, mgm. 10 (an ataractic)
 - D. Triamcinilone mgm. 1 Chlorothen Citrate mgms. 25 (an antihistamine)
- Ascorbic Acid mgm. 75

Cost of one month's therapy with:

Prednisone 5 mgm. b.i.d.	\$9.50) Approximate equivalent therapeutic dosages
C. 1 tab. b.i.d.	25.00	
D. 1 tab. q.i.d.	16.00	

From the above information it is evident that treatment of asthma without an awareness of the cost of the drugs prescribed may put an unwarranted financial burden on the patient. If a patient could be adequately treated by ephedrine gr. $\frac{1}{2}$ t.i.d., he would save about \$500.00 over a 10 year period as compared to treatment with the popular combinations A. and B."

APPENDIX L

"Cost of Gastro-intestinal Drug Therapy [1]
Pharmacy Committee, Canadian Medical
Association, British Columbia
Division
(Second of a Series)

The bulk of drug therapy for gastro-intestinal complaints is directed toward the relief of 'dyspeptic' ulcer-type discomfort arising in the lower oesophagus, stomach and duodenum, or the relief of constipation and lower abdominal discomfort arising in the colon and rectum. Treatment of the former is frequently the same whether or not actual ulcers are demonstrated radiographically, while in dealing with the latter it often makes little difference whether or not x-rays show the changes of spastic colon or diverticulosis. Whatever drugs are prescribed the most important aspects of treatment will nearly always be non-pharmaceutical. Thus, the institution of regular sensible meals with the avoidance of irritants and dietary fads or excesses, the institution of between-meal snacks, the removal of irregular excessive laxative medications, and the attempted correction of personal conflicts, tension and anxiety will achieve more than drugs in most cases. Drug treatment will probably be on a long term basis and therefore, the cost of such therapy is of importance to the patient and doctor.

The following drugs are mentioned because they are popular and the costs are based on a month's treatment with usual doses at a widely used schedule of 'suggested' prescription prices. It has been necessary to use Trade Names because the generic names are often unrecognizable. Because the preparations are widely used it is reasonable and fair that they should be scrutinized from the viewpoint of cost.

Dyspeptic Ulcer Symptoms

The treatment of these complaints with phenobarbitone and an antacid can be achieved for less than \$5.00 a month as follows:-

[1] Ibid., Vol.3, No. 1, January, 1961, p.42.

Phenobarbitone	gr. $\frac{1}{2}$ t.i.d.	\$1.50
Milk of Magnesia	dr. 1 q.i.d.	\$1.50
Magnesium Trisilicate	dr. 1 q.i.d.	\$1.50
Creamalin	dr. 1 q.i.d.	\$2.50
Amphogel	dr. 1 q.i.d.	\$2.70
Gelusil	dr. 1 q.i.d.	\$3.10

The addition of a spasmolytic drug usually increases significantly the cost of prescribing, unless tincture of belladonna is used, which appears rare these days. Trade preparations usually include a sedative with the spasmolytic. Thus, a months supply of Donnatal capsules costs \$4.90 and Neurotrasentin \$4.25. When given with antacids a months treatment will rise to about \$8.00. Somewhat cheaper, if equally effective, Amphogel S.A. tablets, a combination of Amphogel with butobarbitone and scopolamine, cost \$5.15.

Probanthine is popular, but one month's supply of this drug alone costs \$9.35. When combined with phenobarbitone this rises to \$10.25 and presumably an antacid is prescribed also, raising the total cost to \$13.00. An illustration of the high cost of mixtures containing tranquillizers is the preparation of Probanthine with Dartal; a months supply costs \$17.30 and with antacid treatment costs about \$20.00 a month.

Functional disorders of the large gut

Mild laxatives taken regularly in minimally effective quantities form the basis of treatment, and bulk-forming laxatives, mineral oil and water retaining ions such as magnesium are the most satisfactory. Phenolphthalein and cascara are two of the 'pharmacological' drugs often used. They are cheap and often suitable. Relative costs are as follows:-

Milk of magnesia, magnolax or Agarol, about	\$1.50
Cascara, grs. 5 b.i.d.	\$1.80
Metamucil	\$5.65

Dulcolax, a recent popular drug for the treatment of constipation costs \$4.90 for 50 tablets, so that one month's treatment will vary between \$4.00 to \$6.00. "

APPENDIX M

"Cost of Corticosteroid Therapy [1] Pharmacy Committee, B.C. Division, C.M.A.

When used for anti-inflammatory or anti-allergic effects, corticosteroid therapy is often required for a long time, and costs are an important consideration to the patient. The corticosteroid hormones listed below are compared for their relative prices, the costs being based on one month's treatment at an equivalent average dose ('suggested' prescription prices of 'quality control' preparations in March, 1961).

Prednisone	5 mgm.	t.i.d.	\$14.00 and
Prednisolone	5 mgm.	t.i.d.	24.50
Cortisone	25 mg.	t.i.d.	25.00
Dexamethazone	75 mg.	t.i.d.	30.00
Hydrocortisone	20 mg.	t.i.d.	34.00
Triamcinilone	4 mg.	t.i.d.	38.00
Methylprednisone	4 mg.	t.i.d.	38.00

Prednisone may be obtained for less than the \$14.00 price listed above, and in fact for prices approximating \$7.00 a hundred tablets. Almost always, the product so purchased is not manufactured by a company belonging to the Canadian Pharmaceutical Manufacturers Association, whose members maintain rigid controls and tests of each batch of manufactured drugs. Nevertheless, provided that the doctor satisfies himself that the source of the prednisone is a reliable one, he is usually justified in prescribing prednisone in the way that reduces the financial burden on the patient.

There is virtually no convincing medical evidence that any adrenocortical steroid is better than another when prescribed for anti-inflammatory or anti-allergic purposes. Therefore, except for rare occasions, PREDNISONE SHOULD BE PRESCRIBED for the treatment of diseases in which anti-inflammatory or anti-allergic effects are required.

For replacement therapy in Addison's disease or hypopituitary states cortisone or hydrocortisone have advantages over other steroids and should be the steroids of choice.

DON'T FORGET THAT A SIMPLE PRESCRIPTION FOR .5% HYDROCORTISONE IN HYDROPHILIC CREAM OR A STANDARD OINTMENT BASE COSTS A FRACTION OF HYDROCORTISONE 'PROPRIETARY' OINTMENTS AND CREAMS."

[1] Ibid., Vol.3, No. 5, May 1961, p.272.

APPENDIX N

"The Cost of Vitamin Therapy [1]"

Another in the series of articles on the cost of various drug therapies, prepared by the Pharmacy Committee of the B.C. Division.

In view of the very many vitamin preparations marketed by the drug companies the problem of attempting to give an account of vitamin costs appeared difficult. It was finally decided to write to the 14 companies listed most frequently in the vitamin section of the *Vademecum Internationale* and ask for specific information on certain categories of vitamin preparation. Four categories were selected, B-complex, B-complex with C, a multivitamin preparation containing vitamin B₁₂ or liver, and a multivitamin with mineral preparation. The trade name of the preparation, the number of tablets or capsules suggested for daily maintenance dosage, and the 'List Price' of 100 tablets or capsules were requested. Thirteen of the fourteen companies replied and the information is shown in the accompanying table, the costs being based on a month's oral maintenance therapy for adults.

One of the most striking features of the table is the lack of relationship between the complexity of the preparation and the price. Thus a simple B-complex may be more expensive than a vitamin with mineral combination. The other notable feature is the variability in prices between the drug companies. It is very clear from the table that we would be well advised to find out the cost of the particular preparation we wish to prescribe. Furthermore we should be able to find a preparation in any of the groups which will not cost the patient more than \$2 to \$3 a month.

In considering the subject of vitamin therapy one must also raise the question of the indications for vitamins, because the average Canadian diet certainly provides a gross excess of vitamins, and the overwhelming majority of prescribed vitamins almost certainly are given for placebo reasons. This is probably another indication for prescribing less expensive preparations, unless of course part of the placebo effect is due to a high cost. In general one can say that individuals without serious gastrointestinal disease leading to malabsorption will not be improved by vitamin therapy if they are on a normal diet. One can also generalize and state that liver, B₁₂ and folic acid are probably

[1] Ibid., Vol.3, No.12, December 1961, pp.655-56.

best avoided in multivitamin preparations because megaloblastic anemias may be obscured and inadequately treated, leading to subacute combined degeneration. Finally there is little or no evidence that minerals added to vitamins are of any value with the exception of iron, and also calcium for pregnant women. Moreover if there is iron deficiency anemia one must be certain that adequate iron is contained in the vitamin-mineral preparation.

<u>Pharmaceutical Manufacturer</u>	<u>B Complex</u>	<u>B Complex plus C</u>	<u>Multivitamin + B12 or liver</u>	<u>Multivitamin and minerals</u>
A	\$1.30	\$3.10		\$2.70
B		2.10	\$1.55	1.75 to 3.95
C			2.90	1.80
D	2.70	3.10	1.60	2.90
E	1.95		3.70	3.70
F			1.30 to 5.60	1.70 to 5.85
G	5.10	2.75	1.15 to 3.65	1.40 to 3.85
H	3.00	3.25	2.20	4.25 to 5.75
I			3.15	3.15
J		4.95 to 5.95	1.60	1.85 to 4.30
K	4.00	4.50		1.60 to 4.15
L	1.75		1.75	3.25
M				1.15 to 4.75

APPENDIX O

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APPENDIX

Q

Material Collected for Submission to
the Restrictive Trade Practices Commission
in the Course of an Inquiry under Section 42
of the Combines Investigation Act

Relating to

The Manufacture, Distribution and
Sale of Drugs

By

Director of Investigation and Research
Combines Investigation Act

Department of Justice
Ottawa
1961

PREFACE

To avoid misunderstanding, it is emphasized that this is not a report under the Combines Investigation act. It is a Statement of Material collected and analysed by the Director of Investigation and Research for the purpose of being laid before the Restrictive Trade Practices Commission in the course of an inquiry under section 42 of the Act. The text of section 42 is set out on page 1 of the Statement and provides that the Commission is required,

" . . . to consider any evidence or material brought before it for the purpose of the inquiry . . . together with such further evidence or material as the Commission considers advisable and to report thereon in writing to the Minister . . . "

The Commission's report that will ultimately result, is a report under the Act, but a report of a general character to be distinguished from a report concerning an inquiry into alleged contraventions of the anti-combines legislation.

This inquiry under section 42 was initiated by my predecessor, Mr. T. D. MacDonald, Q.C., because of a large number of complaints that prices of drugs in Canada were exorbitant. The inquiry has not been concerned with the level of prices, as such, or whether prices are reasonable. Rather, as the statute contemplates, the inquiry has been concerned with the question whether the prices of drugs in Canada are the result of conditions or practices related to monopolistic situations or restraint of trade.

The officer of the Director's staff in charge of the inquiry under the Director was Mr. F. N. MacLeod, assisted by Miss C. E. Wishart and Mr. L. P. Landry.

(Sgd.) "D. H. W. Henry"

D. H. W. Henry,
Director of Investigation and Research

O t t a w a
February 28, 1961.

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In the matter of the Combines Investigation Act
and
In the matter of an inquiry in connection with
the manufacture, distribution and sale of drugs

CHAPTER I

INTRODUCTION

1. This is a Statement of Material prepared by the Director of Investigation and Research for submission to the Restrictive Trade Practices Commission pursuant to section 42 of the Combines Investigation Act.
2. Following informal complaints about the high cost of drugs, the Director made preliminary inquiries about the sale and distribution of drugs in Canada to determine if a formal inquiry under the Combines Investigation Act was warranted. These preliminary inquiries did not indicate that any price-fixing arrangements existed, but they did indicate that patents are used in such a way as to limit the number of firms engaged in the manufacture and sale of particular drugs; that prices of certain drugs are extremely high in relation to cost of manufacture; that such prices have in some cases remained unchanged for several years despite increased production and use of the particular drug; that there is marked uniformity of pricing among manufacturers; and that, both because of conditions peculiar to the drug field and because of the practices of firms in the field, there is only limited price competition in the supplying of drugs to the public. In view of this preliminary information, the Director started a formal inquiry under section 42 of the Combines Investigation Act on April 14, 1958.
3. Section 42 of the Combines Investigation Act provides:

"(1) The Director upon his own initiative may and upon direction from the Minister or at the instance of the Commission shall carry out an inquiry concerning the existence and effect of conditions or practices having relation to any commodity which may be the subject of trade or commerce and which conditions or practices are related to monopolistic situations or restraint of trade, and for the purposes of this Act any such inquiry shall be deemed to be an inquiry under section 8.

(2) It is the duty of the Commission to consider any evidence or material brought before it under subsection (1) together with such further evidence or material as the Commission considers advisable and to report thereon in writing to the Minister, and for the purposes of this Act any such report shall be deemed to be a report under section 19."
4. The inquiry relates to the sale and distribution of drugs generally and information was obtained about most aspects of the drug industry. However, to keep the inquiry within manageable limits, detailed information about costs,

markups, selling prices and similar aspects was obtained about two general types of drugs only - the antibiotic drugs and the tranquilizer or ataraxic drugs.* These drugs were chosen because they are the two most widely-used types of ethical drugs and because they are the types in respect of which most complaints were received. The choice of these drugs seems to have been fortunate because the information obtained about these drugs appears to illustrate conditions in the drug field generally. This is because these drugs range from new, patented, closely-controlled drugs to older, non-patented drugs which are available from many sources to any drug manufacturer or distributor which wishes to deal in them.

5. Antibiotic drugs were the subject of a study made by the Federal Trade Commission in the United States. Its report, Economic Report on Antibiotics Manufacture, is dated June 1958, was released in August 1958, and covers the period down to the end of 1956. It is undoubtedly the most complete study of the economic aspects of the development of antibiotic drugs which has ever been made and reference to the Report will be made throughout this Statement. It is particularly valuable because the antibiotic drugs (in common with most other drugs) were developed outside Canada and information about such development is not available from Canadian sources. There is no comparable study on tranquilizer drugs available. As far as can be determined, none of these drugs were developed in Canada (although some of the early testing of chlorpromazine (Largactil) on psychotic patients was carried out in Verdun Protestant Hospital in Montreal).

6. This inquiry is concerned principally with ethical drugs rather than proprietary drugs (these terms are explained more fully below). Sales of ethical drugs are subject to various restrictions and differ from sales of ordinary commodities in several ways. Sales of proprietary drug products, on the other hand, are similar to sales of most other commodities. These products are advertised to the public, there are normally many types of similar products available to the purchaser, and the purchaser is free to

*Information about selling prices was obtained by securing price lists from various manufacturers and distributors. This material contains particulars of selling prices, discounts and the like, for the other pharmaceutical products of such manufacturers and distributors, as well as for antibiotic and ataraxic drug products.

choose whichever he pleases. Proprietary drugs will be referred to in the Statement, but the main emphasis will be on ethical drugs and the situation in the ethical drug field.

7. The inquiry was started in April 1958 when the Director asked a number of drug firms to submit returns of information about their businesses and, in particular, about the sources from which antibiotic and tranquilizer drugs were obtained, the costs of such drugs, the costs of preparing dosage forms of such drugs for use by the public, the prices at which such dosage forms were sold, and similar matters. This information was tabulated and analysed and it became apparent that it would be difficult to obtain all the information which was desired because various aspects of the drug industry in Canada are directly affected by conditions outside Canada. However, after further study, it was decided that the inquiry should be continued on the basis of the information available from Canadian sources supplemented by more general information about conditions elsewhere which are directly relevant to the situation in Canada. Requests for information designed to bring the earlier information up to date were sent to those firms which had previously made returns to the Director. Questionnaires along the same lines were also sent to most other drug firms in Canada. Finally, a special questionnaire dealing with promotional and advertising expenses, and expenditures on research, grants to universities and hospitals, quality control and related aspects was sent to a cross-section of firms in the industry. A list of the firms from which information was requested is given in Appendix I. The list also shows those firms which are subsidiaries or branches of foreign firms. As will appear from subsequent portions of the Statement, the fact that many drug firms operating in Canada are subsidiaries or branches has important consequences. The information obtained by return (and by supplementary letters) forms part of the evidence being put before the Commission.

8. It should be noted that the first returns gave information as of about May or June 1958. In the later returns, firms were requested to supply information as to costs and selling prices as at December 31, 1959, so that costs and prices quoted are as of that date. Financial statements were requested for the year 1959, but in a few instances

(particularly where the firm's financial year did not coincide with the calendar year) statements for 1958 were the only ones available and these were supplied to the Director.

9. In connection with prescription pricing practices, besides general inquiries as to the practices in each Province, specific inquiries were made in two Provinces, Ontario and British Columbia. In the course of these, the records of the Ontario College of Pharmacy and of the Pharmaceutical Association of the Province of British Columbia were examined and certain of the records were copied and form part of the evidence being put before the Commission.

10. While the inquiry was in progress, it was learned that the Registrar of the Ontario College of Pharmacy had refused to enter a change of place of business for a druggist, Norman H. Englander, who wished to open a drug store in the premises of Honest Ed (a large discount house) in Toronto. Mr. Englander subsequently applied to the Courts and the Registrar was ordered to make the entry. As it appeared that evidence of this matter was relevant to the inquiry, Mr. Englander was examined on oath before A. S. Whiteley, Esq., a member of the Restrictive Trade Practices Commission, in Toronto on February 12, 1960. The matter is referred to later in this Statement and the Transcript of the hearing forms part of the evidence being put before the Commission.

11. Information was also obtained from many other sources including the Transcript of the evidence given before the United States Senate Subcommittee on Antitrust and Monopoly (Kefauver Committee)*, trade journals, press reports, industry price books, technical reference books, and the like, and by informal interviews with public officials, doctors, and persons connected with the drug trade. Where any specific information so obtained is referred to in the Statement, the source from which it was obtained

*At the time the Statement was being prepared, the complete Transcript of Evidence had not been published and only press reports of certain evidence were available. It is anticipated that the complete Transcript will be available when the matter comes before the Commission. Similarly, at the time the Statement was being written, a Select Committee of the Ontario Legislature was holding public hearings into certain aspects of the sale and distribution of drugs. The Commission will be invited to consider any of the evidence given before the Select Committee which may be relevant to the inquiry.

is indicated. The Commission will be asked to consider various trade journals as illustrative of general conditions in the field such as the number of new drugs and compounds introduced each year, the type of advertising published by the manufacturers, the types of "deals" and special discounts offered from time to time, comment by those in the trade on various matters, and the like.

12. In the case of those firms whose full names are given in Appendix I, abbreviations which are easily recognizable have been used throughout the Statement for the sake of brevity. One firm, Cyanamid of Canada Limited, formerly operated under the name North American Cyanamid Limited and its Medical Products Department was formerly known as Lederle Laboratories Division. The firm still uses the name "Lederle" and the name is widely used in the trade. The firm is referred to as "Cyanamid" throughout the Statement. Another firm, Merck & Co. Limited, sells its pharmaceutical products through its Merck Sharp & Dohme Division. Certain of its products are labelled as Merck Sharpe & Dohme or simply as M-S-D (in a particular design) products. The firm is referred to throughout the Statement as "Merck".

CHAPTER II

GENERAL

13. Drugs are classified in various ways. These classifications are related to the legislation dealing with drugs which is both Federal and Provincial. In very broad terms, the Federal legislation, which is based on the constitutional power in relation to criminal law, is intended to protect the consumer from health hazards and from fraud or deception arising out of the sale of drugs. Provincial legislation, which is based on the constitutional power of the Provinces in respect to property and civil rights, deals with such matters as who may prescribe drugs; the qualifications, testing and licensing of pharmacists; the operation of drug stores; restriction and regulation of the sale of drugs generally and of the sale of poisons, narcotics and prescription drugs in particular; and similar matters. In relation to certain aspects, the Federal and Provincial legislation overlaps.

14. Drugs are affected by many laws, but at the Federal level the three principal statutes dealing with drugs are:

The Opium and Narcotic Drug Act (R.S.C. 1952, Chapter 201).
The Food and Drugs Act (1952-53, Chapter 38).
The Proprietary or Patent Medicine Act (R.S.C. 1952, Chapter 220).

15. The Opium and Narcotic Drug Act need not be considered in detail. Briefly, it classifies certain drugs as narcotics and prohibits their importation, manufacture, distribution and sale except as provided by the Act.

16. The Food and Drugs Act is the most important Federal law dealing with drugs. It also deals with food, cosmetics and devices (i.e., instruments or apparatus for diagnosis, treatment, etc.). As already mentioned, it is based on the Federal power to legislate on criminal matters. In an address at McGill University, the Director of the Food and Drug Directorate pointed out certain consequences of this fact:

" . . .

Because it is criminal law the Act has been drafted as such and it prohibits directly or indirectly certain things as would any other criminal statute.

It is not correct to say, as is so often done, that an article is sold under the Food and Drugs Act. An article not violating the

Act may be sold. The law prohibits things but does not authorize other things. We must bear this in mind. So often officials of the Directorate are asked to approve of a new drug or a label or an action. The law gives no authority for approval of anything or any action. If a product or advertisement does not violate any requirement of the Act or regulations, no objection can be taken to them by the officers of the Directorate. . . ."

(Canadian Pharmaceutical Journal,
May 1957, p. 29-269)

17. Some of the more important provisions of the Act, and the regulations made under it, are the following:

(1) "Drug" is defined according to the intent of the manufacturer or seller. Section 2(f) provides,

"'drug' includes any substance or mixture of substances manufactured, sold or represented for use in

- (i) the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical state, or the symptoms thereof, in man or animal,
- (ii) restoring, correcting or modifying organic functions in man or animal, or
- (iii) disinfection in premises in which food is manufactured, prepared or kept, or for the control of vermin in such premises;"

(1952-53, Chapter 38)

(2) A drug must conform to one of the following standards:

- (i) The standard prescribed by the regulations where such a standard is so prescribed;
- (ii) if no standard is so prescribed, the standard contained in any of the publications listed in Schedule B to the Act (standard works of reference such as the British Pharmacopoeia):
- (iii) if no standard is prescribed or if no standard is contained in any of the named publications, then according to the professed standard under which the drug is sold.

(3) The advertising or representing of any drug as a treatment, preventative or cure for certain named diseases or disorders (set out as Schedule A to the Act) is prohibited. In general, these are diseases or conditions for which it is considered competent medical advice should be sought (cancer, diabetes, heart disease, stomach ulcer, etc.).

(4) The advertising to the general public of any drug which may only be sold on prescription is prohibited by the regulations.

(5) There is a general prohibition of the sale of any adulterated drug or any drug which was manufactured, prepared, preserved, packed

or stored under unsanitary conditions. Broad powers of inspection are now given by the Act.

(6) In addition, certain drugs (set out in Schedules C and D to the Act) may not be sold unless the Minister has certified that the premises in which the drug is manufactured and the process and conditions of manufacture are suitable. This means, in effect, that the named drugs are manufactured under licence and that such manufacture can be strictly controlled.

(7) Further, certain drugs (set out in Schedule E) may not be sold unless the Minister indicates that the batch from which the drug is taken is not unsafe for use. This enables a sample from each batch of the named drugs to be examined before any of the batch is sold.

(8) Labelling is subject to control. In general, such controls are designed to ensure that the drug is properly described on the label and that no unreasonable, unsupported or fraudulent claims are made for the drug.

(9) The regulations contain various provisions relating to prescriptions including a provision that certain drugs (set out in Schedule F to the Act) may only be sold on prescription. It may be noted that Federal legislation did not deal with prescriptions until about 1942. Prior to that date, the restriction of the sale of certain drugs except on prescription was controlled entirely by Provincial legislation. Since 1942, sales on prescription in any Province are subject to the Federal legislation and the legislation of that Province. Thus, there may be no requirement under the Federal legislation that a drug be sold only on prescription, but such a requirement may exist in one or more Provinces. This situation has evoked some criticism and it has been pointed out that it is anomalous, for example, that the same drug may be on open sale in one Province, may be a poison book entry in another, a drug requiring a signature in another, and a drug sold only on prescription in a fourth.

(10) The regulations provide that a new drug may not be sold until certain information about the drug, its method of manufacture, proposed dosage and claims as to its effects, tests as to its safety, and other particulars have been submitted to the Minister. "New drug" is defined

to include a new usage for, or a new method of administration of, a known drug. These regulations enable the Food and Drug Directorate to decide if the new drug should be put on the prescription list, the form of the label and similar matters before the drug actually goes on sale.

18. The Proprietary or Patent Medicine Act allows a manufacturer, subject to certain restrictions, to sell a medicine compounded according to a private formula registered under the Act. A single drug defined in one of the standard books of reference (which are named in the Act) cannot be registered under the Act. Thus, acetylsalicylic acid may be sold under a trade name, as for example, Bayer's Aspirin or Frosst's Acetophen, but it cannot be registered as a patent medicine. A proprietary or patent medicine must not contain a narcotic, an excess of alcohol, or a drug which is a new drug or a prescription drug under the Food and Drugs Act. Also, if a proprietary or patent medicine contains any of certain drugs specified by the Act, the amount of any such drug in each dose must be printed on the label.

19. In general, by requiring registration the Act ensures that the formula will be disclosed to the officials designated by the Act so that the formula may be studied and, if necessary, tested before the medicine is sold to the public.

20. Provincial legislation normally exempts products registered under the Proprietary or Patent Medicine Act. This means that, in any Province where such an exemption is in effect, these products may be sold through other retail outlets besides drug stores.

21. Provincial legislation varies from Province to Province. The Ontario legislation will serve as an illustration. The Act is the Pharmacy Act, 1953, as amended. It establishes the Ontario College of Pharmacy as a body corporate. All registered pharmaceutical chemists are members. Provision is made for the election of a Council and this Council is the governing body of pharmaceutical chemists for the Province. No person may operate a drug store unless he is a registered pharmaceutical chemist or, in the case of a corporation, unless the majority of the directors are pharmaceutical chemists, and unless the majority of each class of shares is owned by and registered in the name of pharmaceutical chemists. (It may be

noted that this would prevent most corporations, including chain or department stores, from operating pharmacies.) There is a general provision prohibiting the sale of all drugs or poisons by anyone except a registered pharmaceutical chemist, but this is subject to some exceptions. The more important general exceptions are those exempting medicines registered under the Proprietary or Patent Medicine Act or any article or substance listed in Schedule B. Schedule B contains a list of common drugs or remedies such as acetylsalicylic acid (in sealed packages only and whether described as Aspirin, Acetophen, or otherwise), cod liver oil, epsom salts, iodine (tincture or solution not more than 2½ per cent), sulphur, turpentine, etc.

22. The Act also contains various detailed provisions about the sale of drugs and poisons and the keeping of records about certain of such sales.

23. It may be noted that in 1959, a revision of Schedule F of the Food and Drugs Act (Federal) deleted corticotrophin, selenium and urethane from the list of drugs for which a prescription is required. However, these drugs were still listed in Schedule C to the Ontario Act and hence could only be sold on prescription in Ontario. This illustrates the overlapping of the Federal and Provincial legislation.

24. Provincial legislation deals primarily with druggists and drug stores, even the provisions dealing with drugs do so from such aspects as who may sell drugs and the like, while the Federal legislation deals primarily with drugs. The Provincial legislation usually sets up a body of pharmacists which, subject to the legislation, governs the practice of pharmacy within the Province. In some Provinces, there is a separate trade association, as for example, the Ontario Retail Pharmacists' Association or ORPA. In certain Provinces, there are local associations of druggists, but no Province-wide organization separate from the official body. However, even where there is a separate Province-wide organization, the governing body still exhibits a dual personality. It carries out its statutory duties of licensing pharmacists and the like, but it also concerns itself with typical trade-association activities and the economic welfare of the druggists as businessmen. In this inquiry, the records of the official body in two Provinces, Ontario and British Columbia, were examined, and show this clearly.

Without expressing any opinion on the matter, it may be pointed out that this situation does raise certain questions, because of the duality of interest of the members of the governing body. Thus, the question of professional ethics, which is a field in which the governing body is normally given certain jurisdiction under the relevant legislation, appears at times to be confused with the question of purely economic and business practices such as aggressive advertising or even simple price competition. Attention is directed to the section below dealing with retail prices.

25. The Federal legislation has nothing to do directly with these aspects. The Federal legislation with which we are concerned is administered by the Food and Drug Directorate. The organization of the Directorate was described by the Director, Dr. C. A. Morrell, in a series of lectures to pharmacists given at McGill University and reported in the May 1957 issue of the Canadian Pharmaceutical Journal, page 28-268. The following is an extract:

"The Food and Drug Directorate is one of the three directorates of the Department of National Health and Welfare. Its chief officer is a director who is responsible to the Deputy Minister and through him to the Minister for all operations and enforcement. The Divisions of the Directorate are the Scientific Services, the Inspection Services, the Administrative Services, the Proprietary or Patent Medicine Division and five regional divisions. The Scientific Services and the Inspection Services are headed by Assistant Directors, the Administration Services has a chief officer and each regional division is in the charge of a regional director.

The Scientific, Inspection and Administrative Services Divisions and the Proprietary or Patent Medicine Division are headquarters divisions located in Ottawa. The Scientific Services is a laboratory division and is responsible for collecting scientific knowledge, both from the literature and from actual work, necessary for proper administration, interpretation and enforcement of the two laws. The laboratories are divided into eleven sections each covering a special field of science and each in the charge of a head of section. These sections are Food Chemistry, Pharmacology and Toxicology, Pharmaceutical Chemistry, Physiology and Hormones, Vitamins and Nutrition, Microbiology, Organic Chemistry, Cosmetic Chemistry and Colours, Animal Pathology and Biometrics. These sections cover the whole range of interests involved in food, drug and cosmetic work. The section heads are responsible for supplying information and advice on all aspects of their specialties and for carrying on research and investigative work needed for the proper administration of the law.

The Inspection Services devises plans and projects in the enforcement field, supplies supervision and guidance to field inspectors, conducts correspondence, reviews labels and advertising including all commercials on television and radio for compliance with the law. Television and radio commercials are reviewed prior to their use but newspaper periodicals and other advertising are examined after their appearance.

The Administrative Services Division is the office of business

management and looks after the purchase of equipment and the stores, prepares the budget, distributes trade information letters, collects information and supplies clerical and stenographic services to the other divisions.

Regional Officers

Each region in turn has office, inspection and laboratory services of its own at regional headquarters. It is the regions that accomplish the greater part of the actual enforcement. The regions have a number of district offices - each in charge of an inspector.

There are five regions in Canada, one of them being the East Central region with a headquarters in Montreal and district offices in Quebec City, Three Rivers, Sherbrooke and Ottawa. Thus, the whole province of Quebec and the eastern tip of Ontario are covered by the East Central region.

District Inspectors

The district inspectors have a prescribed territory to cover and are responsible for all aspects of enforcement in that territory. They must also collect information and give out information to the trade, industry, professions and the public, answer complaints from the public, examine and sample not only domestic articles but also those imported. They maintain relationships in the field with provincial inspectors and with custom officers and officers of other government departments such as Agriculture, Fisheries and R.C.M. Police. Each inspector is supplied with cards giving the name and address of all the manufacturers of foods, drugs and cosmetics and the wholesale and retail outlets for these commodities in his territory. A food and drug inspector therefore knows all of the pharmacies in his district and I dare say the pharmacists all know the inspector.

The inspector in some cases is provided with a small laboratory in which he may do some of the simpler analyses but usually he sends his samples to his regional laboratory where they can be given the full treatment. Results of analyses are reported to him and he takes whatever action may be necessary."

26. As indicated by Dr. Morrell in the excerpt set out above, the Food and Drug Directorate does not check every batch of every drug manufactured in Canada or imported into Canada. Rather, the Directorate knows every factory in Canada and is advised of every importation of drugs and carries out such inspections as are deemed necessary. The inspections are now extended to some factories in foreign countries which produce drugs for sale in Canada.

27. The fact that every batch of drugs sold in Canada is not inspected has some bearing upon the readier acceptance that is generally accorded drugs put out by large, as compared with small, manufacturers. For example, a letter from the files of the Pharmaceutical Association of the Province of British Columbia, written by the Registrar, clearly implies a distrust of the low-cost drugs and pharmaceuticals of "fringe manufacturers" whose products are not subject to continuous quality control measures and the quality of which cannot, therefore, in the opinion of the Registrar, "be guaranteed" (Serial 298). Comment on the alleged superiority of drugs sold under brand names over

drugs sold under generic names was also contained in an article, "What's Behind the Brand Name Drug?" by Stanley N. Conder, General Manager of the Canadian Pharmaceutical Manufacturers Association, which appeared in Drug Merchandising, April 1960, pages 34-35. He said, in part:

"One of the main problems facing Canada's ethical pharmaceutical manufacturers is the deprecators of brand name pharmaceuticals who are attempting to show that considerable savings can be realized by purchasing under generic name. By using fallacious economic arguments and incorrect examples of what they term the high cost of drugs, these suppliers of generic name products are attempting to belie the maxim that 'there is nothing in this world that cannot be made cheaper and sold for less.'

In Canada today, the reputation of the manufacturer is still the best test of reliability, in the field of drugs as in other lines of endeavor. . . .

. . .

The reputable manufacturer of ethical pharmaceuticals requires a heavy investment in laboratory equipment to ensure that his products meet the exacting requirements of his professional clientele. Naturally, the initial outlay and maintenance costs of this equipment alone add considerably to his production costs. And any cut-back in quality control procedures must necessarily be done at the expense of the product.

A reputable manufacturer will spend thousands of dollars in developing a single product and, after it has been marketed under his trade name, will spend thousands more in quality control procedures to ensure that the product continues to meet the high standards required by the medical profession. He could cut expenses by eliminating much of the purity and quality control, but he could no longer be absolutely certain of his product.

As a result, his trade name would become worthless. If all pharmaceuticals were sold only by their generic names, there would no longer be the aura of reliability in the manufacturing of drugs which is so important to the patient."

28. In these and similar comments, there is evidence of a tendency to make the use of a brand name the sole criteria for judging the quality of a drug product. Obviously, the use of a brand name, by itself, is no guarantee of quality. It is the care which was used by the manufacturer which is important. Dr. Morrell made this point in correcting an erroneous report alleging that he considered brand-name products superior. The report of his correcting statement reads, in part:

"When it comes to buying top-quality drugs, the things to check are the ability, facilities, personnel and conscience of the drug manufacturer, Dr. C. A. Morrell, Canada's chief drug inspector, said today.

Neither a brand name nor a drug's generic name is the sole reliable guide to quality, he said.

"The real point is who makes the drug and how it's made - the control system that insures careful and scientific testing for potency and stability."

(Toronto Globe and Mail, August 18, 1960)

29. Sometimes a comparison is made between drugs of domestic manufacture and drugs which are imported. For example, a report of discussion at the Convention of the Ontario Retail Pharmacists' Association carried in the Toronto Globe and Mail on June 7, 1960, included the following:

"S. G. Tuner of London, Ont., retiring association president, said he will present a resolution defending Canada's reputation of having the highest prescription cost in the world and aimed at barring imports of foreign-made generic-name drugs. The resolution will ask the Federal Government to implement inspection and testing of every batch of drugs brought into Canada.

The convention has been told that Canadian drugs are safe because of control by manufacturers. The implication, although not stated, is that imported drugs are not as closely controlled as the Canadian products, and hence not as safe. The resolution is expected to pass with ease and is the main weapon being employed by the drug manufacturers to justify Canadian drug and prescription costs.

The move is being made after the president of one of Canada's largest drug manufacturers, E. Glyde Gregory of Ayerst, McKenna and Harrison, told the convention that Health Minister Waldo J. Monteith has stated already that his department does not and can not make such inspections.

'There is a movement on foot to undermine the North American pharmaceutical industry by the importation of foreign-made chemicals and compounds of obscure origin produced at lower costs than possible in North America,' Mr. Gregory said.

'This movement to the prescription and sale of generic-name drugs from unknown foreign manufacturers versus trade name drugs is being promoted,' he said, 'by selfish motives and interests in the guise of a crusade to improve the lot of the Canadian public.'

30. It is not clear whether the criticism of imported drugs is directed against basic drugs or prepared dosage forms and, in any event, it is clear that such criticism is not intended to be general. Any general criticism of imported basic drugs would be illogical as well as unwarranted because most of the newer and more complicated drugs are imported even by the large ethical drug firms. The Canadian drug industry relies heavily on imported drugs and would be crippled if these imports were cut off. In the account of the Convention as reported in the Globe and Mail, the North American area was spoken of as the domestic area and apparently only those drugs produced in countries outside this continent would be classified as foreign. The great majority of large ethical drug firms operating in Canada are branches or subsidiaries of United States firms and import not only basic drugs from the U.S. but, in many instances, prepared dosage forms and simply package them in Canada. It is quite clear, therefore, that when "foreign"

produced drugs are criticized, it is European drugs which are referred to. Of course, on economic grounds, it makes little difference from which country drugs are imported. Importations from the United States do not assist in developing Canadian production facilities any more than do importations from other countries. There may be other reasons why drugs manufactured in the United States should be purchased in preference to those manufactured in Europe, but if such reasons exist, they do not appear to be economic.

31. Actually, these and similar criticisms appear to relate, in part at least, to a situation which has arisen in recent years. When a new drug is developed and patented in Canada and the United States, the firm or firms holding the patent normally control the sale of the drug and refuse to make it available to other drug firms. However, in some countries, notably Italy, drugs cannot be patented and, hence, can be purchased freely because there are no restrictions arising from patents. Certain Canadian drug firms have purchased supplies of drugs in these countries and have marketed dosage forms of the drugs in Canada in competition with the brand-name products of the patent holders. Usually, dosage forms of a drug which is controlled by one or a few firms are sold at a high price (in relation to actual cost of manufacture). The importer, on the other hand, usually sells its dosage forms at a lower price. The importer also usually sells the drug under its generic name rather than under a brand or trade name. All of these factors are frequently combined in criticism. The importer's product may be disparaged as foreign, cheap and not brand named; but the crux of the matter appears to be that the importer is a small firm which allegedly does not exercise proper quality control. Nobody in the industry would criticize Poulenc which imports chlorpromazine from France and sells it under the trade name Largactil at a high price, rather Largactil is simply regarded as another product of a reliable drug firm and on a par with a domestic product. But when a small dealer imports meprobamate from Italy and sells it under its generic name at a low price, the product is immediately questioned. Regardless of the merits of the criticism, it should be recognized, as the illustration shows, that the criticism is of the small firm's product. The fact that a particular drug is imported is not the issue. Neither is the fact that it is sold under a generic name except on the line of reasoning

that all drugs sold under generic names are necessarily of inferior quality.

32. Certain drugs are criticized as being cheap in the derogatory sense of the word. In some such statements, there appears to be a confusion of terms. Frequently, drugs sold under generic names, or even under brand names, by small manufacturers are sold at lower prices than equivalent dosage forms sold under brand names by the large ethical drug firms; but the actual cost of preparing the dosage forms for resale to the consumer may be practically the same in each case. The small firm's product is cheap as far as selling price is concerned, but not in the sense that it cost less to manufacture, if prime manufacturing costs only are regarded. The large manufacturer may have additional costs for research, advertising and promotion or the like, so that its cost of doing business is greater. Taking these factors into account, it is quite correct to say that the smaller firm's costs are lower, but this does not necessarily imply that its products are cheap in the sense that they are inferior, or that their actual preparation was less costly than in the case of similar products produced by a large manufacturer. For example, a press report of evidence given before a United States Senate Committee included the following:

"One of the most forthright witnesses was Henry H. Hoyt, president of Carter Products, one of the larger companies showing a net profit on sales in 1958 of 20.4 per cent. Hoyt put frankly on the record the cost of making and selling Miltown, a widely used tranquilizer [Miltown is Carter's registered trade name for Meproamate].

His company gets from the wholesaler 5.1 cents for a tablet costing seven-tenths of a cent to manufacture.

With selling, taxes, research, etc., the total cost is 3.9 cents leaving a profit of 1.2 on each pill sold."

(Toronto Daily Star, February 11, 1960)

It would obviously make a great deal of difference whether a small firm's cost of preparing similar tablets was compared with seven-tenths of a cent or 3.9 cents.

33. Much of the discussion on the matter of quality of drugs ranges into the realm of opinion and is characterized by conflicting claims. For example, according to a press article, the Deputy Minister of Health for Nova Scotia was asked by a Legislative Committee if there had been objections about the use of a drug purchased under its generic name. His statement is reported as follows:

". . .

The objections, he said, resulted from the fact that 'a drug detail man took it upon himself to go to the hospital and inform the staff these drugs were not satisfactory.' He added he had been informed this week that the drug being used was as satisfactory as the brand name drug.

". . ."

(Halifax Chronicle Herald, April 13, 1960)

34. Another instance of conflicting claims as to the merits of rival products is afforded by circular letters of Parke-Davis and Intra. Chloramphenicol was introduced about the beginning of 1949 in the United States, and sometime later in Canada, by Parke-Davis under the trade name Chloromycetin. (Presumably the thirteen years referred to below relate back to its original discovery.) The drug is patented and until recently was sold only by Parke-Davis (except for small quantities imported). In 1959, Fine Chemicals obtained a compulsory licence allowing it to manufacture the drug. It sells the drug to Intra which prepares dosage forms which are sold under the trade name Enicol. On March 16, 1960, the Vice-President of Parke-Davis sent the following circular letter to doctors:

"In recent weeks we have received many inquiries about CHLOROMYCETIN^{*} versus chloramphenicol; we are writing you now to set the record straight.

Some have asked if other companies have been licensed by Parke, Davis and Company, Ltd., to manufacture chloramphenicol....The answer is NO!

Some have wanted to know if Parke-Davis is testing and approving chloramphenicols....The answer is NO!

Still others have asked if we have licensed anyone to manufacture CHLOROMYCETIN in Canada....The answer is NO! However, we have been compelled by the Canadian government to consent to another company's manufacturing chloramphenicol, but may we emphasize there has been no transfer of our thirteen years of experience and know-how with CHLOROMYCETIN.

Does Parke-Davis manufacture CHLOROMYCETIN in Canada?....The answer is YES! CHLOROMYCETIN is manufactured in the laboratories of Parke, Davis and Company, Ltd., at Brockville, Ontario.

How has CHLOROMYCETIN's effectiveness been proved?....The efficacy of CHLOROMYCETIN has been proved by clinical use in millions of patients all over the world. Since CHLOROMYCETIN's introduction thirteen years ago by Parke-Davis, the great mass of the clinical investigations, of the in vitro studies, and the related published reports have been based on the experience with CHLOROMYCETIN.

Is the CHLOROMYCETIN used in Canada certified?....The answer is YES!

Are all forms of chloramphenicol sold in Canada certified?....We cannot answer this question because of the many sources of supply, importation from overseas, as well as manufacture in Canada.

^{*}Registered Trade-mark.

Is Parke-Davis familiar with the manufacturing processes and quality control procedures used in the preparation of chloramphenicol sold in Canada?....This question also cannot be answered by us.

We do know about CHLOROMYCETIN, and so do thousands of physicians throughout the world whose confidence in this antibiotic is based on experience.

Some people say all chloramphenicol is CHLOROMYCETIN - but chloramphenicol is not always CHLOROMYCETIN.

Doctor, if there is any other information you would like, please write to us."

Apparently as an answer to the foregoing, the President of Intra then issued the following circular letter:

"Since launching ENICOL, our Canadian made Chloramphenicol B.P., numerous questions were asked of our representatives, to which we feel we owe open, straightforward answers. We therefore state that:

1. INTRA is a wholly Canadian ethical pharmaceutical house, with a policy dedicated to the promotion and sale of drugs made in Canada. When a drug is not made in this country we either see to it that it be so manufactured, or, if this is not feasible, import raw material from reliable sources, to be wrought into the finished dosage form locally. We try to keep our prices competitive and reasonable.

2. ENICOL (Chloramphenicol B.P.) is manufactured for us under contract by Fine Chemicals of Canada Limited in Toronto, Ontario. Since the material involved is patented in Canada and the patent owners refused to grant a licence for its independent Canadian production, the Commissioner of Patents following the requisites of the Canadian Patent Act (Section 41)* granted a licence to the aforementioned company. This he could only do on having sufficient evidence that the applicant was indeed capable of satisfactorily manufacturing Chloramphenicol.

3. The methods of controlling the raw material as manufactured by Fine Chemicals of Canada Ltd. and the controls performed on the finished dosage form by this Company were arrived at through the co-operation and with the satisfaction of our Department of National Health and Welfare, which is entrusted by the Food and Drug Act with the maintenance of the safety of the population.

RESUME:

ENICOL is made from licensed material and is thus legal
ENICOL is subjected to all prescribed controls and must pass them prior to release
ENICOL is available through Canadian drug outlets only
ENICOL is a Canadian product, wholly manufactured in Canada
by Canadian labour and FULLY DESERVES YOUR CONFIDENCE
AND PATRONAGE."

35. In connection with these letters, it may be noted that Fine Chemicals supplies various drugs to many Canadian manufacturers including the large ethical drug firms. For example, Fine Chemicals is licensed by Carter Products Inc. to manufacture meprobamate in Canada, and supplies Ayerst and Wyeth with this drug which these firms sell as Miltown and Equanil respectively.

*(Section 41(3) was set out.)

36. In summary, the Food and Drug Directorate is charged with the inspection of drugs sold in Canada. Regulations provide that before a new drug is sold to the public it must be adequately tested. In the case of established drugs, the Directorate carries out inspections of Canadian factories and of some foreign factories and checks imported drugs. Every batch of every drug is not checked and this has had certain implications for the acceptance of the products of smaller manufacturers or importers. The Directorate carries out such inspections as it feels are necessary to prevent improperly-prepared drugs from reaching the public.

37. The authority of inspectors under the Food and Drugs Act is quite broad. This point should perhaps be emphasized because there is currently a good deal of discussion about this matter in the United States where the Food and Drug Administration is seeking additional authority which, it feels, is necessary to enable it to carry out adequate inspections. There appears to be no question of any weakness in the Canadian legislation.

38. While advertising of proprietary drugs or patent medicines is subject to regulation, the advertising and promotion of such medicines to the general public is allowed and is, of course, vigorously carried out. There is an absolute prohibition of advertising to the general public of drugs designated as prescription drugs under the Food and Drugs Act. There is also a prohibition of advertising drugs as treatments or cures for certain diseases. Because of this prohibition and also, it would seem, because of practice and tradition in the industry, certain drugs, although they may legally be sold without a prescription, are in fact only promoted through professional channels, i.e., to doctors, pharmacists, etc. The situation is also affected by the fact that Provincial legislation prohibits the sale of such drugs except through drug stores. In the result, there are three classes of drugs: the proprietary or patent drugs or medicines which are normally sold both by drug stores and by other outlets; drugs which may only be sold on prescription; and the third class just described. Proprietary or patent medicines are known as such and prescription drugs are known as ethical drugs. There seems to be a difference of opinion as to the correct name for the third class of drugs. They are sometimes referred to as "over the counter" ethical drugs. Actually, since such drugs are not advertised to the public, they are largely unknown to the public and are not normally

purchased except on a prescription or on advice from a doctor or pharmacist. In common usage, the term "ethical drugs" appears to include this class.

Thus, when someone says there are two types of drugs - proprietary and ethical - he is usually including this class under the term "ethical".

39. The term "ethical" also has a rather imprecise but nevertheless well understood general connotation in the drug trade. Thus, a drug store (such as those often found in buildings containing a number of doctors' offices) which specializes in filling prescriptions and does not stock sundry merchandise or have a lunch counter or soda fountain, is frequently referred to as an ethical drug store.

40. Another term commonly used in the industry is "pharmaceuticals" which appears to be a general name for ethical drugs in the wider sense described above.

41. The difficulty with most of the terms of general connotation is that they are used in different senses. It is usually quite easy to determine the meaning intended in any given context, but it is difficult to define the words at large. Thus, the term "proprietary medicine" strictly speaking means a medicine registered under the Proprietary or Patent Medicine Act. However, it is quite common for the term to be used to mean all common drugs advertised to the public and sold without prescription. Thus, Bayer's Aspirin is not a proprietary drug in the strict sense (since it contains only one ingredient and hence cannot be registered under the Act), but in loose usage it would be referred to as a proprietary drug the same as Anacin or Bufferin, both of which are registered under the Act.

42. There are three types of names used for particular drugs. First, there is the chemical name which is descriptive of the chemical composition of the drug. Second, there is the generic name which can best be defined as the common name of the drug. (Regulations under the Food and Drugs Act use the term "proper name" instead of generic name, but with the same meaning.) A generic name becomes settled when the drug is listed in one of the official reference books on drugs. The reference books named in the Food and Drugs Act are:

Pharmacopoea Internationalis
The British Pharmacopoeia
Pharmacopoeia of the United States
Codex Français
The Canadian Formulary

The British Pharmaceutical Codex
The National Formulary

The label of a drug product usually indicates the standard to which a drug conforms. Thus, "B.P." or "U.S.P." after the name of a drug means that the drug conforms to the specifications for that particular drug as laid down in The British Pharmacopoeia or the Pharmacopoeia of the United States respectively. In Canada, if a standard is prescribed under the Food and Drugs regulations, this standard will govern, as noted in paragraph 17(2) above. Third, a particular supplier may sell the drug under a registered trade name. An example of the use of the three types of names for a particular drug is:

Chemical Name - "The hydrochloride of 7-chloro-4-dimethylamino-1,4,4a,5,5a,6,11,12a-octahydro-3,6,10,12,12a-pentahydroxy-6-methyl-1,11-dioxo-2-naphthacenecarboxamide."
(Source: New and Nonofficial Drugs - 1960)

Generic Name - Chlortetracycline HCL.

Trade Name - Aureomycin (registered trade name of Cyanamid).

43. Trade names are used extensively in the drug industry, both for dosage forms of single drugs and for dosage forms which are combinations of several drugs. The use of trade names can be illustrated by Bristol's catalogue of antibiotic and pharmaceutical specialties. The products listed are:

Azotrex (trade name)
Barbonate (trade name)
Bristamin (trade name)
Centrine (trade name)
Di-Streptin (trade name)
Flo-Cillin (trade name)
Kantrex (trade name)
Kectil (trade name)
Neuro-Centrine (trade name)
Oratinic (trade name)
Palacillin (trade name)
Pen-Aqua (trade name)
Pen-Aqua-Mycin (trade name)
Penedrin (trade name)
Penicillin G Potassium (generic name)
Polycycline (trade name)
Saluron (trade name)
Syncillin (trade name)
Tetrex (trade name)
Vycom-B (trade name)

Bristol's catalogue was used as an example because its list of products is short, but it is typical of other firms. Some forms of penicillin, the streptomycins and a few other common drugs are usually listed by their generic names, but the great majority of drugs are sold under trade names.

44. Trade names are particularly important in the case of drugs which, because of patent control, are controlled by one or a few firms. If the promotion of the drug under its trade name is successful, the brand name becomes the accepted name for the drug. Aureomycin appears to be almost as familiar, even to the general public, as penicillin yet very few people probably know the name chlortetracycline.

45. In the field of dosage forms composed of combinations of drugs, there are a limited number of standard, accepted combinations. A simple example would be APC Tablets, one brand of which is sold under the trade name Anacin. Even in the case of the newer and more complicated drugs, certain basic combinations have become standard. The combination of 300,000 international units of procaine penicillin G and 100,000 international units of potassium or sodium penicillin G per dose is an example. This product is listed by many drug firms including Abbott, Ayerst, Bristol, British Drug Houses, Glaxo-Allenbury, Lilly, Merck, Parke-Davis, Pfizer and Wyeth. However, with regard to the newer drugs, there is a tendency for each firm to try to vary any combination form so as to produce a distinctive product which no other firm duplicates precisely. There are, for example, very many combinations of penicillins and sulphas and of penicillins and streptomycins available, each of which usually differs slightly from the others. Advantages are claimed for each and each firm promotes its product (normally under a trade name) as being superior. Similarly, as new drugs are discovered, various combinations of the drug with other drugs are developed and promoted under trade names.

46. The principal reason for the use of trade names is undoubtedly that advertising and promotion of a trade-named product work directly to increase a particular firm's sales. If a firm promotes a drug by its generic name and the drug is sold by several firms, all will probably share in any increased sales; but if it promotes its particular trade-named brand, it will secure more of any increased sales. If the trade-named product is a specialty in the sense that the drug is sold only by one firm or that the precise combination of drugs in a dosage form is sold only by that firm, then any acceptance of the trade-named product by doctors will result in the promoting firm only reaping the whole benefit of any increased sales. As is indicated below, most of the expenditures on advertising and promotion are

in respect of specialty products.

47. Trade names are used in a slightly different way than in most other industries. A trade name is promoted with the object of having it displace the ordinary or generic name. Thus, instead of Upjohn promoting its brand of novobiocin as Upjohn's novobiocin, it promotes its product as Albamycin. This is the usual practice in the industry and, as noted, certain trade names appear to be as well or even better known than the names of the drugs themselves. The distinction between the use of brand names in many other fields and the use of trade names in the drug field may be illustrated by the reported comments of a witness before the Kefauver Committee:

"WASHINGTON. - A pharmacology professor backed the use of brand names in prescription drugs, but criticized the use of trade names.

Dr. Walter Modell of Cornell University Medical College, linked trade names with the registered trade mark for a certain product, but said brand names refer to the name of the manufacturer such as Upjohn brand or Pfizer brand.

. . .

Dr. Modell, who teaches only the use of so-called generic names in writing prescriptions, saw nothing wrong with referring to the brand name with the generic name - Merck's prednisone instead of Deltra tablets, Schering's prednisone instead of Meticorten.

Using trade names that give no idea of the contents of the drug or what chemical family it's in, is not only confusing, but dangerous, he added.

If a doctor prescribes a drug without knowing its make-up he may not apply the principles of that drug group, it was said. He saw the possibility of an accident in prescribing the wrong drug, adding that such an accident would not be a rarity.

The professor alleged there is a tendency to disguise the identity of drugs. Sometimes a drug has as many as 25 or more trade names, he said.

A new form of penicillin, penethicillin, entered the market in recent weeks under six different trade names and in five colours, he added. They are otherwise all identical, Dr. Modell said.

The confusion of using proprietary names has made it possible in a discussion between two specialists in the same field for neither to know that each is talking about the same drug.

. . ."

(New York Journal of Commerce, May 13, 1960)

In ordinary usage in the drug field, no distinction is normally made between a brand name and a trade name and the special names given drug products are usually spoken of as brand names, although technically they are trade names.

48. Recently, a great deal of discussion has arisen about prescribing

drugs (or, more properly, dosage forms of drugs) by generic rather than brand names. This is rather more complicated than is perhaps realized. An important factor is patent control over drugs. Thus, ordinary penicillin G potassium is not subject to patent control and is distributed by many firms, both under its generic name and under a variety of trade names. A doctor prescribing penicillin G potassium tablets for a patient could prescribe simply penicillin G potassium tablets, or he could specify Hylenta Tablets (Ayerst), Palacillin Tablets (Bristol), Falapen Tablets (Frosst), or any of a number of others. In this case, the doctor has a choice and the druggist has access to products of numerous firms so that he too has a choice as to what manufacturer's product he will supply if a particular brand is not specified. The situation is quite different with other drugs. Such drugs are controlled by one or a few firms through patents and (subject to the importations discussed below) are only available from such firms under brand or trade names. Until a compulsory licence was granted recently, chloramphenicol was available only from Parke-Davis under the trade name Chloromycetin. Chlortetracycline is available only from Cyanamid under the name Aureomycin. Oxytetracycline is sold only by Pfizer under the name Terramycin. Chlorpromazine is sold only by Poulenc under the trade name Largactil. Tetracycline is sold by only six firms (through licensing arrangements), all of which sell the drug under trade names. Within the last few years, certain firms have imported many of these patented drugs from Italy and certain other countries (where drugs cannot be patented). One firm has been sued for patent infringement, in respect of its importations and sales, by several of the patent holders in actions which are still before the courts. Certain firms have also obtained compulsory licences under the patents of other firms (Fine Chemicals in respect of chloramphenicol and Frosst in respect of meprobamate, for example). However, apart from the importations mentioned and the limited extent to which the provisions for compulsory licensing have been invoked, the sale and distribution of the drugs protected by patents remain largely in the hands of the holders of the patents and the drugs are only available under these manufacturers' trade names. The principal reason for this appears to be the strong resistance in the trade to the acceptance of the products offered by small importers. Any product of a small manufacturer is at a disadvantage because such a

manufacturer normally cannot promote its product to the same extent as the large firms which send out a continual flow of promotional material and have detail men calling on doctors, hospitals and pharmacists. But apart from this, there appears to exist a concerted campaign to characterize the products of certain firms which offer imported drugs under their generic names as cheap imitations of inferior quality. This has undoubtedly caused doctors and hospitals to hesitate about prescribing and using such products; and unless and until a more widespread demand exists, wholesalers will not stock these products regularly, so that the average druggist or hospital cannot obtain them quickly and easily from a local wholesaler. The products can, of course, be obtained directly from the manufacturers concerned.

49. In the result, there are two distinct situations. First, in respect of some drugs which are not controlled by patents, there are highly-promoted, trade-named products of the larger manufacturers, but equivalent products, under other brand names or simply under the generic name, are freely available. Second, in respect of drugs controlled by patents, equivalent products to the trade-name brands are available in some instances only and then frequently in an incomplete range. Most major drugs are available in various dosage forms, for example, Parke-Davis lists Chloromycetin (chloramphenicol) capsules and Kapseals in three sizes, Chloromycetin Cream (an ointment), Chloromycetin-Hydrocortisone Ophthalmic, Chloromycetin-Hydrocortisone-Polymyxin Ointment, Chloromycetin Intramuscular, Chloromycetin Ophthalmic, Chloromycetin Ophthalmic Ointment, Chloromycetin Otic, Chloromycetin Palmitate Suspension, Chloromycetin Sensitivity Discs, Chloromycetin Succinate and Chlorostrep (Chloromycetin and dihydrostreptomycin) Kapseals. The firms which offer chloramphenicol under another brand name or under the generic name, normally supply only the most commonly-used dosage form, the 250 mg. capsule. Besides not being available in as wide a range of dosage forms, equivalent products of firms which import are not, for the reasons mentioned, as readily available to the average druggist or hospital as are the trade-name products of the large manufacturers. Actually, it is in respect of the patent-controlled drugs that price differences between trade-name products and products sold under the generic name of the drug are most important. The differences in price in the case of other trade-name products, for which numerous equivalents are readily available, tend to be

much less.

50. Officials of the Food and Drug Directorate estimated in 1957 that, counting different brands and different dosage forms, there were about 26,000 different drugs sold in Canada and of these, about 3,000 were registered under the Proprietary or Patent Medicine Act. It was also estimated at the same time that presentations on about 150 new drugs were submitted to the Directorate each year.

51. Drugs are prepared in various dosage forms which are classified according to the method of administration. "Oral" forms are administered through the digestive tract and include tablets, capsules, syrups, etc. "Parenteral" forms are administered by injection directly into the body and are normally in the form of a solution or of a powder with instructions for adding a diluent to form a solution. "Topical" forms are applied externally. An ointment is an example. Dosage forms may consist of one drug (with any necessary binder, diluent, etc.) or of a combination of drugs.

52. Until very recent years, most prescriptions were prepared by the druggist who filled them, i.e., the druggist would measure out each ingredient called for and combine them as directed. Now, the situation has been completely reversed and it is estimated that up to eighty-five per cent, and possibly more, of the prescriptions presented are filled by simply relabelling a package of the dosage form prepared by a manufacturer or, at most, counting out the required number or quantity of the prepared dosage form from a larger container. This is true of all the dosage forms of antibiotic and tranquilizer drugs with which this Statement will deal in some detail.

53. Drugs differ from most other commodities in that, for ethical drugs purchased on prescription or on the advice of a doctor, the person who selects the drug, the doctor, does not buy it. The person who buys it, the patient, ordinarily has no say in the selection of the drug or of the brand of the drug if several brands are available. Moreover, the price of the drug is not likely to be of primary concern to the doctor, his concern is rather the effectiveness of the drug as a treatment for the disease or condition from which the patient is suffering. It is obvious that a doctor's personal appraisal of various drugs will influence his choice and that this, in turn, will depend on the sources of information available to him and the use he makes of these sources.

CHAPTER III

SALES TAX AND TARIFFS

54. Except on sales to public hospitals, drugs are subject to sales tax at the regular rate of eleven per cent.^x The exception in favour of hospitals only applies if the drug is not resold by the hospital and this seems to have been the reason why many hospitals formerly charged patients a flat daily rate which included the supplying of necessary drugs. If the patient was charged separately for drugs, the sales tax would apply. Since the cost of most drugs supplied by hospitals will now be part of the general operating cost of the hospitals and will be paid for under the various hospital plans, presumably virtually all drugs sold to hospitals will be free of sales tax.

55. A few drugs may be imported into Canada duty free, but most are subject to various rates of duty. Certain drugs are dealt with specifically in the Schedules to the Customs Tariff Act, as for example, in Tariff Item

206a:

Tariff Item	British Prefer- ential Tariff %	Most- Favoured- Nation Tariff %	General Tariff %
206a (1) Sera and antisera, toxoids, viruses, toxins and antitoxins; virus and bacterial vaccines, bacteriophage and bacterial lysates; allergenics, liver extracts, pituitary extracts, epinephrine and its solutions, insulin, with or without zinc, globin or protamine; all of the foregoing when imported for parenteral administration in the diagnosis or treatment of diseases of man	Free	Free	Free
(2) Biological products, animal or vegetable, n.o.p., for parenteral administration in the diagnosis or treatment of diseases of animals or poultry, when imported under permit of the Veterinary Director General..	Free	Free	Free
(3) Blood plasma or serum of human origin, or fractions thereof, extenders or substitutes therefor; all of the foregoing when imported for parenteral administration	Free	Free	Free
(4) Materials and articles, except alcohol, for the manufacture of the goods specified in (1), (2) and (3) of this item	Free	Free	Free

56. The great majority of imports come under the general provisions.

Single drugs, of a class or kind made in Canada, are dutiable under Tariff Item 711. Single drugs, of a class or kind not made in Canada, are dutiable under Tariff Item 208t. Combinations and mixtures of drugs are dutiable under

^xA few drugs such as cortisone are exempt from sales tax.

Tariff Item 220. The Items are as follows:

Tariff Item		British Prefer- ential Tariff %	Most- Favoured- Nation Tariff %	General Tariff %
711	All goods not enumerated in this schedule as subject to any other rate of duty, and not otherwise declared free of duty, and not being goods the importation whereof is by law prohibited	15	25	25
	...			
	GATT (1/1/48).....		20	
	...			
208t	All chemicals and drugs, n.o.p., of a kind not produced in Canada.....	Free	15	25
	...			
220	All medicinal and pharmaceutical preparations, compounded of more than one substance, including patent and proprietary preparations, tinctures, pills, powders, troches, lozenges, filled capsules, tablets, syrups, cordials, bitters, anodynes, tonics, plasters, liniments, salves, ointments, pastes, drops, waters, essences and oils, n.o.p.:-			
	(i) When dry	17½	25	25
	GATT (1/1/48)		20	
	...			
	(ii) Liquid, when containing not more than two and one-half per centum of proof spirit	20	40	40
	GATT (1/1/48)	17½		
	GATT (6/6/51)		20	
	(iii) All others	60	60	60
	GATT (6/6/51)		25	
	...			
	Drugs, pill-mass and preparations, not including pills or medicinal plasters, recognized by the British or United States pharmacopoeia, the Canadian Formulary or the French Codex as officinal, shall not be held to be covered by this item.			
	...			

Thus, on drugs imported from the United States, the rates of duty are:

Single drug of a class or kind not made in Canada - 15 per cent.
 Single drug of a class or kind made in Canada - 20 per cent.
 Combinations or mixtures of drugs - 20 per cent (in most cases).

57. In supplying information to the Director, officials of several drug firms stressed the effect of tariffs. One official pointed out that when a drug is imported as a labelled dosage form in substantially the same form as it is sold in the United States, it must be sold to the Canadian subsidiary at its fair-market price in the United States to avoid dumping duties. The official then continued:

"An example of this phenomenon is found in the case of List No. . . . which is sold to wholesale customers in Canada at a price of . . . $\$8.85^x$ per vial and has an estimated cost to . . . Canadian company of . . . $\$8.60^x$ per vial. This results in a cost of goods sold on this particular item of over 97%. After . . . Canadian company pays the cost of delivery to the customer and allows a 2% cash discount, and allocates a pro rata share of sales, promotional and administrative expense to this item, it is apparent that a significant loss is suffered by . . . Canadian company on every sale of List No. . . .

Obviously, the foregoing result does not obtain on every product form or . . . Canadian company would long since have been out of business. The formulae prescribed by Canadian Customs Regulations for determining 'the fair market value' of various materials shipped in bulk to Canada in certain instances permit low import prices -- i.e., raw material costs to . . . Canadian company -- with the result that various of our other product forms seem to have a low cost of goods ratio. These prices at which . . . American company sells raw materials in bulk to . . . Canadian company represent simply a minimal flat mark-up over direct manufacturing cost, and do not reflect an allocation of other normal expenses such as research, product development or royalties. This practice is in complete accord with the provisions of the Canadian Customs Regulations, and is essential in order to counterbalance the high costs to . . . Canadian company of other product forms.

. . .

The Canadian Customs Regulations have another effect which tends to distort the cost ratios of . . . Canadian company. In the pharmaceutical industry, it has long been a practice to distribute a significant volume of free samples to the medical profession, clinics, hospitals and other institutions. Under Canadian Customs Regulations, and in particular the 'anti-dumping' provisions previously referred to, such products or their ingredients must usually, as a practical matter, be imported into Canada at their 'fair market value', as determined by a fixed and arbitrary formula, with duty paid thereon. This has the effect of creating a high cost basis for . . . Canadian company on goods to be distributed free of charge. This high cost of samples is not reflected in any way in the 'cost of manufacturing and packaging' which you have required, because it is carried on our books as 'sales expense'. It is, however, an essential cost of doing business and is a principal factor responsible for the fact that 'sales expense' of . . . Canadian company has ranged from 32.2% to 42.5% of its total sales during the past five years.

. . ."

^xThe actual figures are multiplied by a factor.

CHAPTER IV

PATENTS

58. It is generally accepted that patent laws are designed to encourage invention by rewarding the ingenuity of the inventor. However, in many countries there exist judicial remedies which subordinate patent rights to other general rights. The common device used to limit the rights of an inventor is the compulsory licence. The grounds which justify the use of the device are generally non-use of the patent where this is detrimental in some way to the interests of the public, the need to facilitate the use of improvements or dependent patents, to alleviate specified abuses of patents, and in cases where national defence, public health and other public purposes are in question. In some countries, the provisions for compulsory licensing are contained in the patent legislation, in others in the anti-monopoly legislation, and in at least one other instance in both.

59. In Canada, the Patent Act* provides for compulsory licensing on general grounds applicable to patents in all fields. There are also provisions of general application in the Combines Investigation Act under which the Exchequer Court of Canada may, among other remedies, grant licences in certain situations where a patent or patents have been used to restrain or injure trade.

60. The Patent Act also contains a specific provision relating to compulsory licensing of patents relating to food and drugs. Section 41(3) of the Act reads as follows:

"(3) In the case of any patent for an invention intended for or capable of being used for the preparation or production of food or medicine, the Commissioner shall, unless he sees good reason to the contrary, grant to any person applying for the same, a licence limited to the use of the invention for the purposes of the preparation or production of food or medicine but not otherwise; and, in settling the terms of such licence and fixing the amount of royalty or other consideration payable the Commissioner shall have regard to the desirability of making the food or medicine available to the public at the lowest possible price consistent with giving to the inventor due reward for the research leading to the invention."

It should also be noted that the Patent Act contains a restriction whereby a patent may not be issued for a food or drug produced by a chemical process, but only for the process or for the product when produced by such process.

*R.S.C., 1952, Chapter 203.

This restriction is set out in section 41(1) of the Act:

"41. (1) In the case of inventions relating to substances prepared or produced by chemical processes and intended for food or medicine, the specification shall not include claims for the substance itself, except when prepared or produced by the methods or processes of manufacture particularly described and claimed or by their obvious chemical equivalents."

61. In what appears to be the leading case on the application of section 41(3), Parke, Davis & Co. v. Fine Chemicals of Canada Ltd., (1959) 30 C.P.R. 59, it was argued before the Supreme Court of Canada that the provisions for compulsory licensing contained in section 41(3) only applied to a process patent and not in the case of an added claim for the product when produced by such process. The Court rejected this argument. Rand J. (with whom Abbott J. concurred) said:

"... Such a view contradicts the most significant fact that a new substance, however original and ingenious the idea behind it, cannot be patented alone. Subsection (3) is to be taken to include any new process for producing a new substance, and since the product is process dependent, and as its invention involves the new process, a licence for the latter necessarily involves the right to produce the former: the process necessarily produces the product. The case in which a licence is to be issued is 'of any patent for an invention intended for or capable of being used for the preparation or production of food or medicine'; Benadryl is a substance of medicine and the patented process is intended for its production: Re Glaxo Laboratories Ltd. (1940), 58 R.P.C. 12 . . ."

(30 C.P.R. 62-63)

Martland J. (with whom Locke and Cartwright JJ. concurred) said:

"..."

In my opinion s-s. (3) is not to be interpreted in this narrow manner. In terms it applies to 'any patent' if such patent is for 'an invention intended for or capable of being used for the preparation or production of food or medicine'. The words of limitation of the licence appearing in the subsection, namely, 'a licence limited to the use of the invention for the purposes of the preparation or production of food or medicine but not otherwise', are inserted because the subsection applies not only to inventions intended for the preparation or production of food or medicine, but also to inventions capable of being used for the preparation or production of food or medicine. There may be inventions capable of such use and also of other uses. The licence which may be granted under this subsection is limited to the use of the invention for the preparation or production of food or medicine.

It seems to me that s. 41 must be construed as a whole. Subsection (1) applies to inventions relating to substances prepared or produced by chemical processes and intended for food or medicine. Subsection (3) goes somewhat further and also applies to any patent for an invention capable of being used for the preparation or production of food or medicine. If s-s. (3) were to be construed in the manner suggested by the appellant, it would eliminate from its operation inventions which fell within the operation of s-s. (1). I do not think that such a meaning was intended and the wording of s-s. (3) does not indicate that it must be so construed. The subsection relates to the use of any invention intended for or capable of being used for the

preparation of food or medicine and the provisions as to royalty clearly contemplate the sale of the product produced by such use, for they refer to the making of the food or medicine available to the public at the lowest possible price consistent with giving to the inventor due reward for his research.

. . ."

(30 C.P.R. 66-67)

62. Another argument advanced was that, since Fine Chemicals would only manufacture the basic chemical for sale to other manufacturers which would actually prepare the dosage forms sold to the public, Fine Chemicals was not producing a "medicine". On this point, Martland J. said:

"I agree with Thurlow J. [27 C.P.R. 117] that the word 'medicine', as used in s. 41 of the Act, should be interpreted broadly and I am of the opinion that the product Benadryl is a medicine within the meaning of that section, even when it is in bulk form."

(30 C.P.R. 66)

63. In connection with setting the royalty to be paid under the compulsory licence, Rand J. said:

". . .

The evidence before the Commissioner on damages was quite inadequate to enable him intelligently to arrive at a royalty which would give due weight to all relevant considerations. Where the monopoly in such inventions is so considerably restricted in scope, we should be free from doubt that the royalty allowed is commensurate with the maintenance of research incentive and the importance of both process and substance. That does not appear to me to have been possible on the meagre evidence presented to the Commissioner. The case should be referred back to the Commissioner to enable further matter to be adduced. For that purpose it is not sufficient for the patentee to sit back and, if they only are available, keep important facts undisclosed as being private and confidential; once the Commissioner decides the case to be one for licence, it lies with the patentee, by whatever means are open to him, to present substantial support for the royalty which he claims; in the absence of that he will be in a weak position to complain of any holding by the Commissioner.

. . ."

(30 C.P.R. 63)

64. The effect of the decision in this case appears to be accurately summarized in an editorial note on the case which reads, in part:

"EDITORIAL NOTE: This decision is the first delivered by the Supreme Court of Canada upon the important and controversial s-s. (3) of s. 41 of the Patent Act, R.S.C. 1952, c. 203. As pointed out by Mr. Justice Rand the legislative purpose of the subsection is to ensure that medicines and foods will be made available to the public of Canada at a reasonable price. Arguments in favour of the principle of the subsection were presented to the Royal Commission on Patents, Copyright and Industrial Designs (1955), 23 C.P.R. 146 (Sec. I). United States manufacturers, generally, contend that the subsection works to their detriment by enabling competitors to obtain a right to manufacture products resulting from expensive research without participating in the cost of research incident to unsuccessful experiments (1955), 23 C.P.R. 149 (Sec. I).

The present decision gives the section wide application so that licences may be liberally granted by the Commissioner but the royalty should take into account the costs of research and the importance of the product and the process whereby it is produced."

(30 C.P.R. 60)

65. The Commissioner of Patents has indicated that compulsory licences will be issued under s. 41(3) unless substantial reasons for not doing so are advanced. In a recent application where the points raised in opposition were what the Commissioner termed "the standard type of opposition in all such cases" and were not substantiated by material filed, the Commissioner granted the compulsory licence without holding a hearing (32 C.P.R. 40).

66. The powers of the Commissioner of Patents are also discussed in Parke, Davis & Co. v. Fine Chemicals of Canada Ltd., (1960) 32 C.P.R. 43 (this case is distinct from the case involving the same parties referred to above). In this instance, the Commissioner's refusal to hold a hearing to consider opposition was confirmed in the Exchequer Court. Leave to appeal to the Supreme Court of Canada was refused.

67. Information about compulsory licences issued in respect of patents on certain drugs is contained in a return compiled by the Patent Office in answer to the following question asked in the House of Commons:

"1. Are any patents held for each of the pharmaceuticals of (a) nystatin; (b) tyrothricin; (c) neomycin; (d) dihydrostreptomycin; (e) streptomycin; (f) tetracycline; (g) oxytetracycline; (h) meproamate; (i) chlorpromazine; (j) chlorothiazide; (k) chlortetracycline; (l) erythromycin; (m) chloramphenicol; (n) penicillin?

2. If so, and for each of the said pharmaceuticals what are (a) the names and addresses of the patentees; (b) the dates upon which each patent was issued?

3. Has the Commissioner of Patents issued any licences for the production of any of the said pharmaceuticals?

4. If so, for each such pharmaceutical what are (a) the names and addresses of the licencees; (b) the dates upon which each such license was issued?"

(Hansard, February 10, 1960)

The information contained in the return is shown in condensed form in the chart set out below. The return had the following introductory note:

"A search of the Canadian Patent Office files has revealed the following information on patents for the various pharmaceuticals listed by Mr. Howard. Most of the products listed are governed by Section 41 of the Patent Act, so that many of the patents are directed to processes and product claims dependent on such products, without claims to the products claimed independently of a process. In other instances the compounds may be prepared by biological processes (as contrasted to chemical processes) so that the product is not governed

(cont'd p. 38)

Drug	Patent Holder	Country in which Patentees Resides	Number of Patents Held	Date of		Licence Holder	Date of Licence
				First Patent Issued	Held		
Mystatin	Research Corporation	U.S.A.	1	3.11.53			
	Olin Mathieson Chemical Co.	U.S.A.	1	9.2.50			
Tyrothricin (Gramicidin) (Tyrocidine)	Merck & Co.	U.S.A.	1	22.1.46			
	P. W. Wilcox & B. B. Jatul	U.S.A.	1	29.4.52			
	Parke, Davis & Co.	U.S.A.	2	25.5.54			
	Nopera Chem. Co.	U.S.A.	1	29.5.56			
	Merck & Co. Inc.	U.S.A.	3	20.10.53			
Neomycin	Chas. Pfizer & Co.	U.S.A.	3	14.8.56			
	Chemie Grunenthal G.m.b.H	Germany	1	17.4.56			
	Nopera Chem. Co.	U.S.A.	1	29.5.56			
	The Upjohn Co.	U.S.A.	2	16.9.53			
	Chas. Pfizer & Co.	U.S.A.	3	16.1.51			
	Societe des Usines Chimiques Rhone-Poulenc	France	2	4.10.55			
Dihydrostreptomycin	Merck & Co. Inc.	U.S.A.	12	1.1.52			
	Olin Mathieson Chemical Corp.	U.S.A.	2	24.1.56			
	Sharpe & Dohme Inc.	U.S.A.	1	29.5.51			
	Lepetit S.p.A.	Italy	1	14.9.54			
	Farbwerke Hoechst						
	Aktiengesellschaft vormals Meister Lucius & Bruning	Germany	1	27.11.56			
	Parke, Davis & Co.	U.S.A.	1	24.4.51			
	Eli Lilly & Co.	U.S.A.	1	15.6.54			
	Ayerst, McKenna & Harrison Ltd.	Canada	1	30.12.52			
	Rutgers Research & Endowment Foundation (Assignee)	U.S.A.	1	12.2.52			
Streptomycin	E. R. Squibb & Sons	U.S.A.	1	22.7.52			
	A. E. Staley Mfg. Co.	U.S.A.	3	25.8.53			
	The Distillers Co. Ltd.	Scotland	2	8.9.53			
	H. H. Thornberry and H. W. Anderson	U.S.A.	1	26.4.55			
	Merck & Co. Inc.	U.S.A.	31	9.1.51			
	Chas. Pfizer & Co.	U.S.A.	9	25.8.53			

<u>Drug</u>	<u>Patent Holder</u>	<u>Country in which Patentees Resides</u>	<u>Number of Patents Held</u>	<u>Date of First Patent Issued</u>	<u>Licence Holder</u>	<u>Date of Licence</u>
Streptomycin (Cont'd)	Olin Mathieson Chemical Co.	U.S.A.	4	24.1.56		
	Sharpe & Dohme Inc.	U.S.A.	1	29.5.31		
	Farbwerke Hoechst					
	Aktiengesellschaft vormals Meister Lucius & Bruning	Germany	1	27.11.56		
	Abbott Laboratories	U.S.A.	1	1.9.53		
	Chemie Grunenthal G.m.b.H.	Germany	2	10.5.55		
	Bristol Laboratories	U.S.A.	2	25.3.58		
	American Home Products Corp.	U.S.A.	1	2.3.54		
	Schenley Industries Inc.	U.S.A.	4	31.8.54		
	Eli Lilly & Co.	U.S.A.	1	15.6.54		
Tetracycline	Chas. Pfizer & Co.	U.S.A.	9	23.3.54		
	American Cyanamid Co.	U.S.A.	18	7.6.55		
	Bristol Laboratories	U.S.A.	5	8.1.57		
	Olin Mathieson Chemical Co.	U.S.A.	1	9.2.60		
Oxytetracycline	Chas. Pfizer & Co.	U.S.A.	16	8.6.54		
	Koninklijke Nederlandsche Gist- & Spiritusfabriek N.V.	Netherlands	1	28.6.55		
	Eli Lilly & Co.	U.S.A.	1	17.1.56		
	American Cyanamid Co.	U.S.A.	2	31.5.55		
Meprobamate	Carter Products Inc.	U.S.A.	1	26.2.57	Charles E. Frosst and Company	19.8.58
	Merck & Co. Inc.	U.S.A.	1	9.9.59		
Chlorpromazine	Societe des Usines Chimiques Rhone-Poulenc	France	2	13.12.55		
	(Note: Patents issued to the same company directed to related products)		34 / 1 re-issue	6.3.51		
Patents related to Chlorpromazine	Upjohn Co.	U.S.A.	1	3.6.52		
	G. D. Searle & Co.	U.S.A.	2	28.7.53		
	Sandoz A. G.	Switzerland	1	7.10.58		

<u>Drug</u>	<u>Patent Holder</u>	<u>Country in which Patentee Resides</u>	<u>Number of Patents Held</u>	<u>Date of First Patent Issued</u>	<u>Licence Holder</u>	<u>Date of Licence</u>
Chlorothiazide	Merck & Co. Inc.	U.S.A.	10	9.6.59		
Chlortetracycline	American Cyanamid Co. Chas. Pfizer & Co. Societe des Usines Chimiques Rhone-Poulenc	U.S.A. U.S.A. France	25 1 2	3.11.53 18.12.56 14.6.55		
Erythromycin	Eli Lilly & Co. The Upjohn Co. Abbott Laboratories	U.S.A. U.S.A. U.S.A.	5 5 2	18.8.53 2.10.56 4.6.57		
Chloramphenicol	Parke, Davis & Co.	U.S.A.	13	11.12.51	Fine Chemicals of Canada Ltd.*	1.4.59
	Janos Kollonitsch, Valeria Gabor and Andor Hajos Monsanto Chemical Co. Chinoin Gyogyszer es Vegyeszeti Termekek Gyara R.T. C. F. Boehringer & Soehne G.M.B.H.	Hungary U.S.A. Hungary Germany	1 1 1 1	3.9.57 28.1.58 3.9.57 10.11.59		
Compounds related to Chloramphenicol or derivatives thereof	Farmaceutici Italia, S.A. Sterling Drug, Inc. E. I. du Pont de Nemours & Co. Parke, Davis & Co.	Italy U.S.A. U.S.A. U.S.A.	5 2 4 18	19.5.59 16.7.57 26.6.56 11.12.51	Fine Chemicals of Canada Ltd.*	1.4.59
	Chinoin Gyogyszer es Vegyeszeti Termekek Gyara American Cyanamid Co.	Hungary U.S.A.	2 1	22.7.58 31.5.55		

*Licences granted under seven patents. Terms not agreed upon
at request by the parties for a postponement.

<u>Drug</u>	<u>Patent Holder</u>	<u>Country in which Patentee Resides</u>	<u>Number of Patents Held</u>	<u>Date of First Patent Issued</u>	<u>Licence Holder</u>	<u>Date of Licence</u>
Penicillin*	Merck & Co. Inc.	U.S.A.	22	23.11.48		
	Commercial Solvents	U.S.A.	15	30.11.48		
	Chas. Pfizer & Co.	U.S.A.	2	31.5.49		
	Abbott Laboratories	U.S.A.	1	30.8.49		
	Eli Lilly & Co.	U.S.A.	11	26.9.50		
	American Cyanamid Co.	U.S.A.	9	30.1.51		
	Heyden Chem. Corp.	U.S.A.	1	20.2.51		
	Governors University of Toronto	Canada	3	24.7.51		
	E. R. Squibb & Sons	U.S.A.	2	11.9.51		
	Wyeth Incorporated	U.S.A.	2	11.9.51		
	Ayerst, McKenna & Harrison	Canada	4	20.1.53		
	The Distillers Co.	Scotland	6	2.10.51		
	American Home Products	U.S.A.	9	23.2.54		
	Glaxo Laboratories	England	4	1.6.54		
	Shell Development	U.S.A.	1	16.3.54		
	Bristol Laboratories	U.S.A.	5	5.10.54		
	Lovens Kemiske Fabrik	Denmark	4	28.8.56		
	Gewerkshaft Rheinpreussen	Germany	1	16.10.56		
	Farbwerke Hoechst	Germany	4	27.11.56		
	Boots Pure Drug Co.	England	2	15.3.55		
	Chemie Grunenthal	Germany	2	10.5.55		
	Schenley Industries Inc.	U.S.A.	3	29.7.58		
	Leo Industrie Chimiche					
	Farmaceutiche	Italy	1	27.1.59		
	Les Laboratoires Francais	France	1	7.7.59		
	C. E. Frosst & Co.	Canada	1	13.10.59		
	Societe des Usines Chimiques Rhone-Poulenc	France	1	27.10.59		
	The Upjohn Co.	U.S.A.	2	4.11.58		
	A. E. Staley Mfg., Co.	U.S.A.	2	28.7.53		
	Radio Corp. of America	U.S.A.	1	11.11.52		
	Rheinpreussen Akt. fuer Bergbow und Chemie	Germany	1	17.3.59		

*No patent has issued for penicillin itself but many have issued directed to various means of preparing and purifying penicillin and its pharmaceutically-active derivatives. It is these patents that are listed.

by Section 41, and product claims independent of a process may have issued to patent. For some of the products many different patents have issued directed to different processes of preparing or separating the product, to improvements in the products, to derivatives of the product or to specialised compositions in which the product is used. Most of these are listed below though because of the complexity in searching all possible aspects of such inventions it may be a few are not included. We have not, for instance, listed patents for animal fodders in which some pharmaceuticals are now incorporated to promote weight gains in livestock. The search has been complicated by the fact that many of the products went under several different names during their early development.

We have given the names of the owners of the patents concerned at the time the patents were issued. They may, of course, be assigned or reassigned to others since that date."

68. The Royal Commission on Patents, Copyright and Industrial Designs (The Ilsley Commission) in its Report on Patents of Invention* made several recommendations regarding the patenting of foods and medicines and compulsory licensing. It recommended that the restrictions on the patenting of foods and medicines be removed (i.e., that product patents be issued on these products). It also recommended the following compulsory licensing provisions:

6. (1) Without prejudice to the foregoing provisions of this Act, where a patent is in force in respect of -

- (a) a substance capable of being used as food or medicine or in the production of food or medicine; or
- (b) a process for producing such a substance as aforesaid; or
- (c) any invention capable of being used as or as part of a surgical or therapeutic device;

the Patent Tribunal shall, on application made to it by any person interested, order the grant to the applicant of a licence under the patent on such terms as it deems advisable, unless it appears to it that there are good reasons for refusing the application.

(2) In settling the terms of licences under this section the Patent Tribunal shall endeavour to secure that food, medicines, and surgical and therapeutic devices shall be available to the public at the lowest prices consistent with the patentees deriving a reasonable advantage from their patent rights.

(3) A licence granted under this section shall confer upon the licensee the right

- (a) where the invention is itself a food or medicine or is or is part of a surgical or therapeutic device, to produce it;
- (b) to use the invention for the purposes of the production of food or medicine; or
- (c) to use the invention for the purposes of the production of, or part of, a surgical or therapeutic device; and to use and sell what has been so produced, but no other right.

*Report on Patents of Invention, Royal Commission on Patents, Copyright and Industrial Designs, Ottawa, 1960.

(4) In this section 'medicine' includes anaesthetics and analgesics.

. . ."

(pp. 92-93)

69. The Commission considered the question of whether compulsory licences should issue as of right and said:

". . .

We considered whether we should recommend that the section provide for licences of right so that the Patent Tribunal would not be concerned with the question whether 'there are good reasons for refusing the application.' One of the objections to leaving this question of good reasons to the Patent Tribunal is that lengthy arguments may result, entailing delay and expense.

However, on the whole, and on balance, we think that it would be desirable to continue, for the time being at least, the principle contained in subsection (3) of section 41 of our present Act that licences shall not be of right but that the licensing authority may, if good reason to the contrary, or good reasons for refusing the application, are established, refuse to grant the licence. This principle is embodied in section 41 of the United Kingdom Patents Act of 1949. The guidance the courts have given as to what may be regarded as good reasons for refusing the application is decidedly [sic] vague, and perhaps necessarily so, as the future situations which may arise are unpredictable and almost infinite in number. Circumstances can readily be imagined where the licensing authority might reasonably consider that in the public interest the licence should not be granted. It occurs to us that this would normally be so if it were established that there was a probability that the granting of the licence would result in an increase rather than a decrease in the cost of the food or medicine to the public, or that the applicant had no bona fide intention of embarking upon the production of the food or medicine. There may be other circumstances the proof of which before the Commissioner would point to the conclusion that the granting of a licence would not be in the public interest which do not suggest themselves to us, at least in a form which would enable us to express them without complex qualifications.

One disturbing possibility is that delaying tactics on the part of patentees who oppose applications for compulsory licences will develop. In view of the possibility of large profits on some patented foods and medicines, particularly drugs, the field is such that a substantial delay may be of great financial advantage to the patentee. With respect to the possibility of such delays we make the following recommendations:

. . . [rules to eliminate delays were recommended.]

(3) That if it is found, notwithstanding the foregoing that there are serious delays, considerations be given to amending the section so that licences will be issuable as of right.

. . ."

(pp. 96-97)

Among other provisions for the granting of compulsory licences generally, the Commission recommended that the grounds on which a licence might be granted be extended to include:

"(d) that use has been made of the exclusive rights and privileges conferred by the patent, or the patent and one or more other

patents, in such a way that the Exchequer Court could on an information exhibited by the Attorney General of Canada by virtue of section 30 of the Combines Investigation Act, make an order directing the grant of licences under any such patent;"

(p. 74)

70. The following brief comments on relevant patent legislation in other countries are based (except for the references to Neumeyer in the case of the United States) on Patents Throughout the World (Second Edition) by William Wallace White and Byfleet G. Ravenscroft, and the page references in brackets are to this book.

United States of America

The United States patent legislation makes no distinction as to the patenting of medicines nor does it provide any means of compulsory licensing. However, compulsory licensing has developed as a "judicial doctrine" in antitrust cases even though the antitrust laws do not contain any "express provisions on the subject"^x. In 1945, the decision in Hartford - Empire Co. v. United States "settled that in a civil proceeding under the Sherman Antitrust Act, the Court may order the defendants to grant licenses under their patents, subject to the payment of a reasonable royalty, where such relief appears appropriate to achieve the antitrust objective of restoring the balance of competition."^x

Dr. Neumeyer also states in his discussions of the use of compulsory licensing for reasons of public health that:

"... In 1945, American courts intervened, to a limited extent, in this field in connection with the Steenbock vitamin-D irradiation patents. In Vitamin Technologists v. Wisconsin Alumni Research Foundation, the court held the patents in question invalid and then went on to criticize severely the refusal of the patentee to grant licenses for use of the invention in irradiating oleomargarine with vitamin-D to prevent rickets, and suggested that this would be a valid basis for refusing to enjoin defendant in the infringement suit. Shortly thereafter, the Antitrust Division intervened in a second infringement suit involving the same patents, and this intervention resulted in an antitrust consent judgment which opened up the patents to compulsory licensing. . . ."^{xx}

Great Britain

"The Comptroller may grant working licenses under patents in respect of articles of food, medicines, and surgical and curative devices to interested parties at any time."

(p. 165)

^xDr. Fredrik Neumeyer, Compulsory Licensing of Patents under Some Non-American Systems, prepared for the Committee on the Judiciary, United States Senate, S. Res. 236, Study No. 19, p. 37.

^{xx}Ibid, p. 48.

Austria

"Unpatentable - . . . articles serving for human nourishment; medicines or disinfectants; and substances produced by chemical processes, although the processes themselves may be patented."

(p. 51)

Belgium

No special provisions relating to drugs are reported. Presumably they may be patented. There is no express provision for compulsory licensing, but it is suggested that the provisions of certain international agreements, to which Belgium is a party, apply. (These would not have particular relation to drugs.)

Denmark

"Unpatentable - Inventions of no substantial importance, and those contrary to law, morality or public order; inventions of medicines, of articles of food or refreshment, of methods of preparing articles of food, and of chemical compounds although chemical processes are patentable."

(p. 125)

France*

"Pharmaceuticals, medicines, and processes and machines for producing the same are patentable."

(p. 147)

"A compulsory license may be granted where a patent has not been worked for three years and there is no good reason for such non-working. Special licenses may be granted where pharmaceutical products, the process for which is patented, are not deemed properly available to the public."

(p. 148)

Germany (The German Federal Republic)

"Unpatentable - . . . (2) Inventions relating to articles of food, whether for nourishment or enjoyment, medicines, and also to substances prepared by chemical processes, in so far as the inventions do not relate to a definite process for the preparation thereof."

(pp. 153-54)

Italy

" . . . all kinds of medicines and processes for the production thereof have been held to be unpatentable."

(p. 204)

Japan

"Inventions of food products, or beverages, medicines or chemicals are not patentable but new processes of manufacturing them are patentable; . . ."

(p. 209)

*Certain changes in the French law relating to patents on drugs are reported in the July 1960 issue of the Journal of the Patent Office Society.

Netherlands

"Unpatentable - . . . Homogeneous substances, such as pure chemical compounds, alloys and solutions or dispersions are not patentable per se, but a patent granted for a process for the manufacture of such substances may cover also the substances themselves when manufactured according to the process."

(pp. 251-52)

Norway

"Unpatentable - . . . and articles of food, medicine or chemical combinations, although the processes themselves may be patented."

(p. 270)

Rumania

"Unpatentable - . . . inventions relating to articles of nourishment for men and to fodder for beasts; inventions of pharmaceutical compounds or medicines or disinfectants; . . ."

(p. 302)

Sweden

"Unpatentable - . . . inventions relating to articles of food, medicines, or chemical compounds, although the special processes for their manufacture may be patented."

(p. 346)

Switzerland

"Unpatentable - . . . all chemical substances and also homogeneous products obtained by processes involving chemical reactions (alloys are patentable); medicines and non-chemical processes for the manufacture of same; articles of food or beverages for man or beast (the processes of manufacture of same are patentable)."

(pp. 349-50)

71. It will be noted that drugs cannot be patented in Italy and that only chemical processes can be patented in Denmark. These countries appear to be the chief sources of supply for those firms which import drugs which they could not obtain otherwise because of patent control in Canada. This matter is referred to elsewhere in the Statement. Rumania is mentioned above because there have recently been reports about importations of drugs from that country. No imports from Rumania of the specific drugs about which information was obtained in this inquiry were reported to the Director. The information referred to above indicates that drugs cannot be patented in Rumania.

CHAPTER V

DEVELOPMENT OF NEW DRUGS WITHIN RECENT YEARS

72. The drug industry has changed radically within recent years, largely it would seem, because of the discovery of new drugs, particularly those commonly referred to as wonder drugs. An assessment of the importance of these drugs from a scientific or medical point of view is beyond the scope of this Statement. The Statement is concerned with the economic effects and these have been extremely important in various ways. A very brief outline of the discovery and development of some of the so-called wonder drugs is given in the following paragraphs.

73. The first of the modern wonder drugs was sulfanilamide. Its widespread acceptance and use may be said to date from a medical report read at a meeting in November 1936 which told of what, in the light of the medical knowledge of that date, were almost unbelievable results achieved by its use.

74. Actually, the first experimental work was done with a dye called Prontosil developed by I. G. Farbenindustrie in Germany. When its medical usefulness was established, chemists at the Pasteur Institute in Paris broke Prontosil down chemically and discovered that the sulfanilamide molecule, which it contained, was the ingredient which possessed the medicinal properties. This was important because sulfanilamide was a known drug (although its ability to fight infection had not been suspected) and hence could not be patented or controlled through patent arrangements. Moreover, the drug was relatively simple and easy to manufacture.

75. Once the value of sulfanilamide was discovered, chemists immediately went to work modifying its chemical structure to obtain other varieties of the drug which might work even more effectively. As a result, numerous sulpha drugs have been developed. The sulphas are still widely used, particularly in combination with various antibiotics.

76. The first antibiotic, penicillin, was discovered by Sir Alexander Fleming in 1928. He observed the antibacterial action of a mould which had accidentally contaminated an agar-plate culture of a staphylococcus species he was studying at St. Mary's Hospital in London, England. The mould was isolated and tentatively identified as belonging to the genus penicillium. When grown in a culture it produced a substance which appeared to be effective

against many types of bacteria, but it was unstable and easily destroyed. Early attempts to concentrate it failed. Fleming published a report of his discovery, but at the time no one, including Fleming himself, appeared to have realized the significance of the discovery.

77. Over the next decade, isolated experimental work was carried out by various researchers largely, it would appear, as part of more general inquiries. Most of this work was done in England but some was also done in the United States. For example, the definite identification of the exact type of penicillium mould which Fleming had isolated was made by Dr. A. H. Thom of the U.S. Department of Agriculture. In any event, a group of researchers at Oxford University, headed by Dr. H. W. Florey, became convinced of the potentialities of the new drug. Their work had apparently been planned prior to the outbreak of World War II, but after war broke out Dr. Florey believed that the drug would be of particular value in treating wounded soldiers and that maximum efforts should be made to develop it. In 1941, he visited the United States to discuss production of the drug with American scientists. As a result of this visit, the production of penicillin was encouraged and assisted by various agencies of the United States Government as part of the war effort. It is undoubtedly due to this fact that commercial production of penicillin was achieved within a few years.

78. The first small quantities of penicillin became available in the United States in the Spring of 1942. From then until July 1943, all available penicillin was reserved for clinical testing by a small number of accredited investigators. In July 1943, all penicillin produced in the United States was placed under allocation order by the War Production Board. It was used to supply the needs of the armed forces of the Allies and, to a limited extent, was supplied to private physicians in selected cases. Production began to increase progressively each month and by May 1944, limited sale of the drug through hospitals was permitted. From this date onward, production increased steadily.

79. The increase in production was due to several factors. Better strains of penicillium were discovered as a result of testing different strains and of inducing mutations in strains already known. Better media for use in the fermentation process were found. Also, at first, penicillin

was produced in shallow dishes such as flasks, pans, etc. This was necessary because the reaction was a surface reaction which required oxygen. Later, a method of deep-vat fermentation was developed. This has made possible the use of tanks of up to 30,000 gallon capacity. Thus, cost of production has been reduced in two ways, first, more efficient methods of production have been developed (large tanks for small flasks, etc.); second, the yield from a given amount of broth has been increased tremendously (one estimate given in the FTC Report is that yield of penicillin increased at least 142 times between 1945 and 1956 and may have increased several times this amount).

80. As already noted, penicillin was the first antibiotic drug discovered. Its discovery and development did two things. First, it opened up a whole new field of the study of micro-organisms, the boundaries of which are still being extended as the search for newer antibiotic drugs goes on. Second, because of the similarity of the processes of producing other antibiotic drugs, the improvement of the methods of producing penicillin made it easier to produce such drugs. On this second point, the FTC Report quotes a British scientist who said:

"It is perhaps worth pointing out that these advances did something more than improve penicillin production. They made available not only plant but also 'know-how' about aerobic aseptic fermentation on a manufacturing scale for submerged culture, so that the problems of producing on a similar scale further antibiotics, as they were discovered and became of practical interest to the medical profession, were half solved before they were even posited. And this applies not only to antibiotic production, but also to the manufacture of at least one other compound of wide medical importance, namely, cyanocobalamin (vitamin B₁₂), as well as to operations needed during the manufacture of riboflavine. . . ."

(A. L. Bacharach in Penicillin, Its Practical Application, second edition, London, 1950, p. 11)

81. A writer in International Record of Medicine (Volume 168, Number 7, July 1955, p. 450) estimated that between 3,000 and 4,000 antibiotics had been described in medical literature up to that date. Of these, he listed eighteen as "useful". In carrying out its study, the FTC found that, for various reasons, records for the period prior to 1948 were incomplete and that it was only able to secure accurate information for the period beginning with 1948. The Commission reported that seventeen types of penicillin and twenty-two other antibiotics were produced at one time or another between 1948 and 1956 in the United States. In 1956, eleven penicillins and eighteen other

antibiotics were being produced. Of these, four penicillins and four other antibiotics were introduced in that year. The complete list showing the years in which each was produced is given in Table I which is based on Chart 1 which appears at page 69 of the FTC Report:

TABLE I
YEARS IN WHICH EACH ANTIBIOTIC WAS PRODUCED 1948-1956

	<u>1948</u>	<u>1949</u>	<u>1950</u>	<u>1951</u>	<u>1952</u>	<u>1953</u>	<u>1954</u>	<u>1955</u>	<u>1956</u>
Penicillins									
Triethylamine	X		X						
Calcium	X	X	X	X	X				
Potassium	X	X	X	X	X	X	X	X	X
Sodium	X	X	X	X	X	X	X	X	X
Procaine	X	X	X	X	X	X		X	X
Aluminum		X	X	X	X		X	X	X
Ephedrine		X							
Dibenzyl				X	X	X	X	X	
I-Ephenamine				X	X		X		
"O" Potassium				X	X				
Benzathine				X	X			X	X
Chloroprocaine "O"						X	X	X	X
"V"								X	X
"V" Benzathine									X
"V" Potassium									X
"V" Hydrabamine ...									X
"O" Sodium									X
Other Antibiotics									
Streptomycin	X	X	X	X	X	X	X	X	X
Dihydrostreptomycin	X	X	X	X	X	X	X	X	X
Bacitracin	X	X	X	X	X	X	X	X	X
Chlortetracycline .	X	X	X	X	X	X	X	X	X
Chloramphenicol ...	X	X	X	X	X	X	X	X	X
Tyrothricin		X	X	X	X	X		X	X
Oxytetracycline ...			X	X	X	X	X	X	X
Viomycin			X	X	X	X	X	X	X
Neomycin				X	X	X	X	X	X
Polymyxin				X	X	X	X	X	X
Actidione					X	X	X	X	
Erythromycin					X	X	X	X	X
Fumagillin					X	X	X		
Carbomycin						X		X	
Tetracycline						X	X	X	X
Nystatin							X	X	X
Anisomycin								X	
Cycloserine								X	X
Amphotycin									X
Oleandomycin									X
Novobiocin									X
Candididin									X

Source: FTC Data Requests, 1956 and 1957.

82. The antibiotic drugs differ in importance and their positions, relative to each other, have changed as new ones have been discovered and introduced. Table II set out below, taken from the FTC Report,* shows the

*Based on Table 6, p. 67.

situation in the United States in 1956 as compared with 1948:

TABLE II

OUTPUT OF LEADING ANTIBIOTICS AND PER CENT
OF TOTAL OUTPUT - 1948 AND 1956

Antibiotic	1 9 4 8		1 9 5 6	
	Number of Pounds ^o	Per Cent of Total	Number of Pounds ^o	Per Cent of Total
Penicillins	155,873	64.9	1,059,704	34.4
Streptomycin	80,737	33.6	148,999	4.8
Dihydrostreptomycin	2,989	1.2	492,173	16.0
Chlortetracycline .	661	.3	560,663	18.2
Oxytetracycline ...	-	-	324,614	10.5
Tetracycline	-	-	220,074	7.1
Chloramphenicol ...	46	(x)	85,408	2.8
Erythromycin	-	-	70,913	2.3
All others	26	(x)	118,825	3.9
Total	<u>240,332</u>	<u>100.0</u>	<u>3,081,373</u>	<u>100.0</u>

^oThe normal measure of penicillin is international units of potency. The conversion to pounds for the purposes of this and other tables was done by the FTC on the basis of published potency ratios which are fully explained in the FTC Report.

*Less than 0.1 per cent.

Source: FTC Data Requests, 1956 and 1957.

83. The table shows that, as of 1956 and for the United States, penicillin was the most important antibiotic. Streptomycin and dihydrostreptomycin, which were the next antibiotics to be produced in quantity, were also quite important. The group of so-called "broad-spectrum" antibiotics had become increasingly important and, taken as a group, accounted for a greater proportion of total antibiotic production than penicillin. (The broad-spectrum antibiotics are chloramphenicol, tetracycline, oxytetracycline and chlortetracycline.)^{xx} Of the remaining antibiotics, erythromycin was the most important.

84. It is not known precisely what changes have occurred since 1956. The returns received in the inquiry mention the following additional antibiotics as now being sold in Canada:

Amphotericin B.
Demethylchlortetracycline
Gramicidin
Griseofulvin
Kanamycin

^{xx}Another broad-spectrum antibiotic, demethylchlortetracycline (Declomycin), has been introduced by Cyanamid since the FTC Report was issued.

Ristocetin
Spiramycine
Thioridazine
Thiostrepton
Vancomycin
Various new forms of penicillin including the
new synthetic penicillin, penilethicillin
potassium.

It seems probable, too, that there have been changes in the relative importance of various antibiotics. For example, the number and variety of new dosage forms of the tetracycline group which have and continue to be brought out indicate that this group of antibiotics is now very widely used.

85. One of the main objectives of early research on the antibiotic drugs was to discover a method of producing the drugs by chemical synthesis rather than by fermentation, as the former method would be cheaper. However, until 1958 and 1959, production by synthesis was only accomplished commercially in the case of chloramphenicol. Certain types of penicillin were produced synthetically in laboratory experiments, but commercial production continued to be by fermentation. It would seem that the tremendous improvement in methods of fermentation made the search for methods of synthesis much less urgent. In 1958, a method of synthesizing penicillin* was developed in the United States and such penicillin, for which advantages are claimed, is now on the market. Also, in 1959, researchers in England succeeded in isolating the "heart" of the penicillin nucleus. Some authorities in the field say that this will allow new types of penicillin to be tailor-made to meet specific requirements. The assessment of these developments raises scientific questions which are beyond the scope of this Statement. Our point of interest is that, up to the present, most antibiotics have been produced by fermentation.

86. Most of the basic patents on antibiotics were taken out in the United States. The summary set out in the next few paragraphs is based on the FTC Report. Information obtained by the Director indicates that those firms holding U.S. patents also hold Canadian patents covering the same product or process, as the case may be.

87. When penicillin was first discovered, there was no provision for patenting a drug in England and Sir Alexander Fleming did not apply for a

*It is understood that the starting materials for the synthesizing process are still obtained by fermentation.

patent in the United States (or elsewhere). Subsequent discoveries relating to improved methods of production of the drug made by U.S. Government research workers were patented, but licences under these patents were issued freely. An important later development, procaine penicillin, was patented by Lilly, but licences under this patent have been widely issued. In summary, what may be termed the "old" penicillins were either not patented or, if patents were issued in connection with them, licences under these patents have been issued freely.

88. Since 1950, a number of new types of penicillin have been discovered. Among these are benzathine penicillin, phenoxymethyl penicillin (penicillin V) and hydrabamine penicillin. The patent on the first is held by Wyeth which settled patent interferences by agreeing to license Pfizer, Lilly and Bristol. The patent on the second is held by Lilly which has licensed Wyeth only. The patent on the third is held by Abbott which has not granted any licences to any other manufacturer. In summary, what may be called the "new" penicillins are subject to tight patent control.

89. Streptomycin was patented by Merck which assigned the patent to Rutgers University. Dihydrostreptomycin was patented by Merck. Licences under these patents have been issued freely.

90. The first broad-spectrum antibiotic to reach the market was chlortetracycline. It was developed and patented by American Cyanamid Company and marketed as Aureomycin. No licences to manufacture and sell chlortetracycline as such have been issued. However, chlortetracycline may be used to manufacture tetracycline and licences to manufacture chlortetracycline for use in the manufacture of tetracycline have been issued to Pfizer and Bristol.

91. The next broad-spectrum antibiotic to reach the market was chloramphenicol. It was developed and patented by Parke-Davis and marketed as Chloromycetin. No licences under the patents have been issued to any other manufacturer in the United States. In Canada, Fine Chemicals has obtained a compulsory licence under the provisions of section 41(3) of the Patent Act.

92. The third broad-spectrum antibiotic is oxytetracycline. This was developed and patented by Pfizer and is marketed under the name Terramycin. No other manufacturer has been licensed under Pfizer's patents.

93. Tetracycline, which is very similar to chlortetracycline and oxytetracycline, appears to have been developed or discovered almost simultaneously by several firms which each applied for patents. There was some doubt that the substance was patentable (because it had been created previously in the manufacture of chlortetracycline) and all applications for patents were at first rejected by the United States Patent Examiner. Subsequently, the U.S. Patent Office was persuaded that the product was patentable and, after litigation, agreement was reached among the several claimants. In the result, patents were issued to Pfizer, licences to manufacture and sell were issued by Pfizer to Cyanamid and Bristol, and licences to sell only were issued by Pfizer to Squibb and Upjohn.

94. Of the remaining antibiotics, erythromycin is one of the most important commercially. The patent rights are held by Lilly which licenses Abbott and Upjohn.

95. Next in the parade of wonder drugs is cortisone which revolutionized the treatment of arthritis and which has since been found to be effective in treating many other conditions. The drug is a hormone and a steroid (so called because its chemical structure is built on the steroid nucleus). It came into general use in 1949, but at first was very difficult to produce and very expensive. It was developed and patented by Merck, but because Merck's processes conflicted with a number of existing patents in the field, a royalty and cross-licensing arrangement was worked out with the holders of these patents. Methods of production were improved by Merck and by Upjohn and cost was reduced. Merck also discovered hydrocortisone, a closely-related product which had advantages in certain conditions. Then Schering discovered prednisone and prednisolone which it marketed under the trade names of Meticorten and Meticortelone. These are modifications of cortisone and hydrocortisone respectively which are much more effective and have fewer side effects. There has been some litigation about patents but, by agreement or licence, Merck, Upjohn, Pfizer and Parke-Davis may also produce prednisone and prednisolone.

96. The steroids and hormones have been known and studied for years. (Apparently a false rumour during the war that Nazi pilots were able to fly at great heights after being given certain hormones stimulated research on hormones by the Allies.) An article in Fortune Magazine for August 1958

entitled "Schering's Structural Roulette" tells the story of Schering's development of prednisone and prednisolone and touches on the development of cortisone generally. Among the interesting points made in the article is that,

"Then [in 1955], with the introduction of two new drugs [prednisone and prednisolone], Schering's sales shot from \$19,426,000 to \$45,960,000 that year and its after tax income rose a stunning 432 per cent. Last year sales ran well over \$80 million and profits reached the fat figure of \$15,400,000."

(p. 102)

97. Later in this Statement, some analysis of costs, markups and selling prices of antibiotic and tranquilizer drugs, about which detailed information was obtained, will be attempted. No detailed information was obtained about cortisone or any related product. However, for comparative purposes, it may be noted that evidence before the recent Senate Committee in the United States was to the effect that, for Schering's prednisolone sold under the name Meticortelone, the cost of manufacturing 100 tablets (five mg.) was \$1.57. The selling price to a retail druggist was \$17.90 and the suggested retail price was \$29.83. The list or suggested selling price of the same tablets in Canada is \$33.13.

98. Next on the list of wonder drugs are the tranquilizers. Professor Kennedy of the Faculty of Pharmacy, University of Toronto, said, in the article referred to below, that the term "ataraxic" was coined by Dr. Howard D. Fabing and Professor Alister Cameron in the United States in 1955. It has since come into general use as a descriptive term for the tranquilizer drugs. Some authorities think that the use of the terms "tranquilizer" and "ataraxic" is unfortunate because the terms are not sufficiently precise. For example, the editors of New and Nonofficial Drugs - 1960 make the following comment:

"Among the drugs included in this and other chapters of the book are those used principally for their effect on the psyche and which have been variously described as tranquilizing, ataraxic, calmative, neurosedative and pacific. Although various meanings have been associated with these terms, all can be regarded as more or less synonymous with 'peace of mind.' This obviously refers to a state which is psychological rather than pharmacological, since it can be produced by a variety of drugs which either depress or stimulate the central nervous system or which exert only a peripheral effect on organ structures. Thus, a tranquil state can be accomplished by nonspecific sedation (alcohol, barbiturates), by analgesics (acetylsalicylic acid, morphine), by skeletal muscle relaxants (mephenesin, meprobamate), by autonomic suppressants (chlorpromazine, reserpine) and by pharmacological stimulants such as amphetamine. In the broadest sense, therefore, the reversal of any clinical

disorder, even by drugs with only peripheral effects (epinephrine in asthma and digitalis in cardiac decompensation), can produce psychic benefits by relieving anxiety. Hence, such terms as 'tranquilizer' or 'staraxic' have no specific or useful pharmacological connotation. For these reasons, and to the extent to which their pharmacological action is known, drugs which are proposed for use as psychotherapeutic agents can be more scientifically classified on the basis of their predominant pharmacological action in man."

(p. 330)

99. Professor Kennedy also gave a brief description of the discovery of three of the first tranquilizer drugs:

". . .

The first three substances possessing this new selectively sedative action were discovered more or less by accident. It is also interesting to note that three very different tranquilizers (reserpine, chlorpromazine, and meprobamate) were discovered and tested by different companies at almost the same time. Reserpine was to be marketed only as a new hypotensive agent by the Ciba Co. (as Serpasil). However, in June 1953, this company's laboratories received a new shipment of monkeys. Alfred E. Earl, the Veterinarian in charge, gave this shipment injections of reserpine and found that the animals were 'calmed' yet remained coordinated. In 1953, Nathan S. Kline, Rockland State Hospital, treated approximately 400 patients (mostly schizophrenics), some with reserpine and some with placebos. The results were astounding. Twenty-two percent of the patients (chronically psychotic females) who had not responded previously to other treatment were sufficiently improved so that they could be discharged.

Chlorpromazine was discovered by the Rhône-Poulenc company of France while searching (by synthesizing new compounds of basic antihistamine structures) for a compound that would potentiate the action of sedatives. In the course of use the French psychiatrists noted that chlorpromazine seemed to cut through the psychotic state. This report was somewhat casually received by the American psychiatrists who at the time did not evidence too great an interest. Smith, Kline and French had found that Thorazine (chlorpromazine) was highly effective in the prevention of vomiting. This factor was to be the major sales promotion idea. However, Lehmann and Hanrahan (Verdun Protestant Hospital, Montreal) reported the successful use of chlorpromazine in the treatment of psychotic patients.

Meprobamate was developed as a result of initial work in synthesizing preservatives for use in penicillin preparations. Frank M. Berger had noticed that one of the compounds tested on mice had a muscular relaxant effect. In the search for a more efficient muscle relaxant, Berger and Bradley developed mephesisin. Further work on mephesisin-like compounds resulted in the synthesis of meprobamate.

". . ."

(Canadian Pharmaceutical Journal,
August 1957, p. 61-501.)

100. The tranquilizers are very new and the list of such drugs is constantly being expanded. They have been classified in various ways; one classification is given in an article referred to below. Many of these drugs have other uses, for example reserpine is also used in the treatment of hypertension. There seems to be an increasing tendency to combine

tranquilizer drugs with other drugs in dosage forms designed to meet specific conditions. Thus, Schering manufactures Sterotril Tablets which combine prednisone (one of the cortisone drugs mentioned above) and perphenazine (a tranquilizer) as a treatment in rheumatic, dermatologic and respiratory diseases "when anxiety and tension retard recovery".

101. In an article entitled "Tranquilizing and Related Drugs; a Guide for the General Physician"^x by Drs. B. C. Schiele and W. Benson, the following description of tranquilizing drugs is given:

". . .

Tranquilization is somewhat different from sedation. Sedative agents affect the cortical as well as the subcortical areas in the brain. In contrast, the tranquilizers act principally on the lower brain areas. Their tranquilizing effect may be described as the production of emotional calmness and relaxation without significant sedation, hypnosis, motor impairment or euphoria; and yet they characteristically produce some sedative effect, particularly in certain persons and if large doses are used. This sedative effect, however, differs from that of the regular hypnotic drugs. It is more transitory, and even when deliberately fostered by the utilization of large doses, such as might be done to control an excited patient, it is not of the same depth or quality. To illustrate, a previously excited patient who is now tranquilized may sleep readily and for long periods, but he is easily awakened. When awake, his eyelids may droop and he may appear somewhat 'doped,' but he is mentally clear, rational and cooperative and has relatively good motor coordination. He is usually calm and reasonable and may have good insight into the fact that he recently was disturbed and upset. This remarkable change in demeanor and attitude could not have occurred with the drugs previously available. If barbiturates were given in sufficient quantities to control such an excited patient, he would be so sedated that he could not function adequately either mentally or physically. Further, to continue giving large amounts of barbiturates would be hazardous, whereas relatively heavy administration of most tranquilizing agents usually can be continued over a period of months if necessary.

". . ."

(p. 485)

The authors then classify tranquilizer drugs as major tranquilizing drugs and minor tranquilizing drugs and, as related drugs, refer to new nonbarbiturate sedatives and calmatives, antidepressive drugs, and drug combinations.

The major tranquilizers are listed as:

(a) Phenothiazine Group

<u>Generic Name</u>	<u>Trade Name</u>
Chlorpromazine	Thorazine (Largactil in Canada)
Promazine	Sparine (also Intrazine, Promwill, Pro-tran in Canada)
Mepazine	Pacatal
Prochlorperazine	Compazine (Stemetil in Canada)

^xPostgraduate Medicine, Volume 23, Number 5, p. 484 et seq., May 1958.

(a) Phenothiazine Group (Cont'd)

<u>Generic Name</u>	<u>Trade Name</u>
Perphenazine	Trilafon
Triflupromazine	Vesprin
Promethazine	Phenergan

(b) Rauwolfia Group

Reserpine	Serpasil (also Sandril, Alserin in Canada)
Rescinnamine	Moderil (U.S. only)
Deserpidine (Recanescine)	Harmonyl

Of these, the authors say:

" . . .

The major tranquilizers are the drugs of choice in excited, delusional or disorganized states, including those of toxic and organic origin. Chronically or severely incapacitated psychoneurotic patients, many of whom are ambulatory schizophrenics, often fail to benefit from the minor tranquilizers but may be helped by one of the major tranquilizers.

. . ."

(p. 488)

The minor tranquilizers are listed as:

(a) Alkanediol Type

<u>Generic Name</u>	<u>Trade Name</u>
Meprobamate	Miltown
	Equanil
Phenaglycodol	Ultrane (Acalo in Canada)

(b) Diphenylmethane Type

Hydroxyzine	Atarax
Benactyzine	Suavetil (Actozine, Levol in Canada)
Azacyclonol	Frenquel

Of these, the authors say:

" . . .

The minor tranquilizers are the preferred drugs in the common nervous states. Because of their relative safety, many physicians prefer to try them first in any ambulatory case. Their calming action is usually sufficient to benefit the majority of persons with nervous tension, mild depression, psychosomatic disorders, and the like.

. . ."

(p. 489)

New nonbarbiturates and calmatives are listed as:

<u>Generic Name</u>	<u>Trade Name</u>
Methylparafynol	Dormison
Ethinamate	Valmid
Glutethimide	Doriden

(Cont'd)

<u>Generic Name</u>	<u>Trade Name</u>
Methypylon	Noludar
Ethchlorvynol	Placidyl
Petrichloral	Periclor (U.S.)
Ectylurea	Nostyn
Oxanamide	Quiactin

102. The article also lists antisupressive drugs and drug combinations, but these need not be referred to here.

103. The information reported to the Director in 1958 on the ownership of patents in respect to tranquilizer drugs included the following:

<u>Generic Name</u>	<u>Firm</u>	<u>Trade Name</u>
Benactyzine	Canadian Pharmacal Horner	Benetranc Levol
(No patents reported.)		
Captodiamine Hydrochloride	Ayerst	Suvren
(Ayerst reported that H. Lundbeck & Co., Denmark, had applied for patents.)		
Chlorpromazine	Poulenc	Largactil Larga-Dex
(Canadian patents held by Rhône-Poulenc, Paris.)		
Deserpidine	Abbott	Harmonyl
(Abbott purchased from parent company; did not report either it or parent holding a patent.)		
Ethchlorvynol	Abbott	Placidyl
(Abbott purchased from parent company which manufactures under licence under U.S. Patent 2,746,900.)		
Hydroxyzine	Pfizer	Atarax
(Pfizer reported its parent is licensed under Canadian Patents 674,532-6 held by Union Chimique Belge.)		
Mepazine	Warner-Chilcott	Pacatal
(Warner-Chilcott pays a royalty on net sales to Chemische Fabrik Promonta GMBH, Hamburg, Germany, which, it says, holds the Canadian patent.)		
Meproamate	Ayerst	Miltown
	Cyanamid	Pathibamate (a combination)
	Elliott-Marion	Trelmar
	Frosst	217 MEP (a combination) 282 MEP (a combination)
	Intra Merck	Tranquiline Meproamate with Prednisolone
Wyeth		Equanil
(Canadian Patent 537,437 held by Carter Products, Inc. which licenses Ayerst, Cyanamid, Elliott-Marion, Merck, Wyeth and Intra. Frosst was granted a compulsory licence under section 41(3) of the Patent Act.)		
Oxanamide	Merrell	Quiactin
(Canadian Patent 511,233 is held by The Wm. S. Merrell Company, Cincinnati, Ohio.)		

<u>Generic Name</u>	<u>Firm</u>	<u>Trade Name</u>
Perphenazine (Schering reported an application for a Canadian patent has been made.)	Schering	Trilafon
Phenaglycodol (Lilly reported that this drug is not patented.)	Lilly	Acalo
Prochlorperazine (Patent applied for by Rhône-Poulenc.)	Poulenc	Stematil
Promazine	Elliott-Marion	Promazine
	Intra	Intrazine
	Mowatt & Moore	Pro-Tran
	Powell	Promazine
	Wyeth	Sparine
	Rougier	Portabex-Tran (a combination of which promazine is only one of several ingredients.)
(According to Wyeth, Canadian Patents 483,976, 511,686, 472,002 and 536,567 are held by Rhône-Poulenc. Elliott-Marion, Intra, Mowatt & Moore, Powell and Rougier did not report any patent arrangements.)		
Rauwolfia (No patent arrangements reported.)	Mowatt & Moore Powell	Rauserpen-Root Raumanitin
Reserpine	Canadian Pharmacal	Reserpine
	Ciba	Serpasil
	Elliott-Marion	Tranplex
	Frosst	Alserin
	Intra	Reserpine
	Lilly	Sandril
	Mowatt & Moore	Reserpine
	Pitman-Moore	Ebserpine
	Powell	Reserpine
	Parke-Davis	Serfin
	Upjohn	Reserpoid
(Ciba reported:		

"Although reserpine was isolated by CIBA in 1952, patent protection was only obtained on July 26, 1956. In the intervening period the product was manufactured and sold by a great number of competitors who were later on licensed by CIBA when patent protection was obtained. The following companies are licensed to produce or sell reserpine in Canada:

Riker Laboratories Inc.
Pfizer (Canada) - Division of Pfizer Corp., U.S.A.
Fine Chemicals of Canada
S. B. Penick & Co.
Eli Lilly

We also recognize world licenses granted by our U.S. and Swiss Associates. Attached is a list of the firms who sell reserpine in Canada and who have declared to us that they buy their material from our licensees or from licensees of our parent organizations either in the United States or in Europe."

Then follows a list of thirty-two firms and the names of their suppliers. These include most of the firms listed above. (It does not include Elliott-Marion which said it is not licensed, or Frosst which, however, reported it is licensed by Ciba.)

104. The drugs mentioned, the sulphas, the antibiotics, cortisone and related drugs, and the tranquilizers are illustrative of the developments in the field within a relatively short period. There were numerous other important drugs developed; a few, such as Salk vaccine, might also be classified as wonder drugs. Others were less spectacular, but all contributed to the revolution in the drug industry.

105. As already indicated, no attempt to appraise the scientific or medical effects of the discovery of these drugs will be made here. Admittedly, these represent important discoveries and have given the medical profession valuable new weapons in the fight against disease. From an economic point of view, the following seem to be some of the more important effects:

(a) The volume of business done by drug firms increased sharply. The New York Times, in an article published at the beginning of 1959, cited generally accepted figures when it stated that sales in the United States climbed from \$300,000,000 before World War II to nearly \$2,500,000,000 in 1958 (New York Times, February 15, 1959, section 3, p. F1). This represents an eight-fold increase in about twenty years (not taking account of the change in the value of the dollar).

(b) The increase has been largely due to the development of new drugs. For example, according to the FTC Report, manufacturers' sales of antibiotic drugs alone in the United States in 1956 amounted to \$301,000,000. This was equal to the dollar volume of sales of all drugs before World War II.

(c) Increased sales were reflected in generally increased profits in the industry. While most firms in the field shared these increased sales and profits, those firms which succeeded in developing one or more of the newer drugs as a specialty made spectacular gains. The article in the New York Times already referred to comments on this aspect also:

"There have been few authoritative surveys of the drug industry. A recent one was made by David L. Babson & Co., investment counsel of Boston. Babson made the telling point that a major discovery can have a 'powerful' impact on the earnings of a company. These figures show the effect on sales and earnings within two years after the introduction of a new product:

<u>Company and Product</u>	<u>Year</u>	<u>P. C. Sales Incr.</u>	<u>Jump in Pre-Tax Net Inc.</u>
Pfizer, antibiotic	1949	110	132
Smith, Kline for treatment of mental disturbances	1954	100	220
Schering, treatment of arthritis	1955	320	860
Carter, treatment of mental disturbances ..	1955	200	515
Parke, Davis antibiotic	1949	86	220"

It seems clear that the antibiotic drugs referred to in the case of Pfizer and Parke-Davis are Terramycin (oxytetracycline) and Chloromycetin (chloramphenicol) respectively. The other drugs are, presumably,

Meticorten and Meticortelone for Schering (see Fortune Magazine, August 1958, "Schering's Structural Roulette"); Thorazine for Smith, Kline & French; and Miltown for Carter Products (see Barron's Magazine, March 31, 1958, "Less Tranquility"). Thorazine in the U.S. is the same as Largactil in Canada.

(d) Research and expenditures on research have increased greatly. The reasons for this appear to be accurately summarized in an address by W. Furness Thompson, Vice-President, Research and Development Division, Smith, Kline & French, reported in the Journal of the Patent Office Society (Volume XLI, Number 1, January 1959, pp. 70-71):

" . . .

In other words, I think we can fairly say that our industry places a premium upon research, and incidentally, when we examine the reason for this, I think we will also see why the patent system has profound implications on the rapid progress of medical advances.

Why this intense preoccupation with research?

In the first place in our business as in any business there is a strong urge to advance technologically, to develop new products and improve old ones. But I like to think we have perhaps even a little greater motivation because our work is so closely related to matters of life and death and human suffering. The quicker we can get a better product, the more lives and suffering we save.

Secondly, there are some purely practical factors which motivate our research. In few other fields is the pressure of competitive research so relentless. The past 20 years has been a fantastic record of breakthroughs in the medical sciences, which so intimately affect our industry. The opportunity for progress has been great, and the pharmaceutical industry has made and exploited these opportunities to the fullest. Disease entities which historically were never considered targets for chemotherapy have yielded to drug therapy. The result, of course, is intense pressure to stay in the lead.

Then, the high obsolescence rate is a constant spur. One has no time to sit back on one's laurels after introducing a major new product. Like the Strategic Air Command's latest bomber, the product is often on the way out as soon as it rolls off the line.

Then, there is also the simple fact that our industry has found research to be profitable. There are unavoidable risks, but as a whole the investment pays off. We couldn't continue at the high rate we do if such were not the case. One figure I might cite is that at SKF 60% of our sales are in products less than three years old; 80% in products less than six years old.

Patents quite obviously are essential to protect this investment. They make it worthwhile for the research-minded pharmaceutical house to undertake the risks of research knowing that their efforts will be protected. . . ."

(e) If advertising and promotion had merely expanded in direct proportion to the increase in sales, the increase would have been, as we have seen, about eight-fold. But more fundamental changes appear to have taken place. Formerly, the drugs available were limited in number and their effects were well-known. As an increasing number of new drugs became available, not only were they unknown to the medical profession in general, but knowledge of their potentialities and of any undesirable side effects was constantly being added to. This meant that if a new drug was to achieve maximum usefulness, the medical

profession had to be informed both of its curative qualities and of any dangers in its use. Moreover, as has been noted, new drugs have proved to be very high-profit items. Thus, both from a service or humanitarian and from an economic point of view, it was essential that manufacturers inform the medical profession about new drugs. The situation became even more complicated because, as the new drugs were developed, manufacturers brought out numerous dosage forms embodying combinations of various drugs, each of which was claimed to have peculiar advantages. Within limits, the new drugs compete with each other. Thus, an antibiotic and a tranquilizer are normally used for entirely different purposes. But in many cases, it may be a matter for the physician's judgment whether one antibiotic or another, or whether one tranquilizer or another will be prescribed. The manufacturers have met the problem of reaching the doctors by direct promotion based on the use of detail men and backed by a programme of free samples, lavish promotional literature, and extensive advertising in professional journals. It is impossible to get comparative figures of costs of promotion in recent years as compared with expenditures prior to the present wonder-drug era. However, all available evidence points to the fact that such promotion is on a scale never before known. An instance of its extent is illustrated by the statement in the FTC Report that, in introducing Aureomycin (chlortetracycline) in the United States in 1948, Cyanamid distributed ten carloads of free samples to about 142,000 physicians at an estimated cost, for the drug alone, of two million dollars (FTC Report, p. 140). Some comment on advertising and promotional expenditures by drug firms in Canada is set out below. It is sufficient to note here that it sometimes costs more to advertise and promote the drug products of a firm than it does to manufacture or purchase such products.

(f) There has been a significant change in the role of the pharmacist in so far as actually preparing prescriptions is concerned. Formerly, most prescriptions dispensed by a pharmacist were compounded by him in his dispensary. The number of basic drugs was relatively limited and these, for the most part, were mixed on the spot when the doctor prescribed a combination of drugs for a particular patient. Now, most dosage forms are prepared by the manufacturer, and the pharmacist simply relabels the manufacturer's package or dispenses the necessary quantity out of a larger package. There appear to be several reasons for the increasing preparation of dosage forms at the manufacturing level. The most important is probably that dosage forms of certain of the newer drugs, and particularly combinations of such drugs, require more elaborate control and handling than can conveniently be done at the pharmacist's level. It is obviously more practical for a complicated combination of, say, several antibiotic drugs and several sulphas to be prepared and sealed in a factory than to have a pharmacist make up a dozen capsules or a small quantity of solution containing the combination. In some cases, only minute quantities of certain drugs are used and it would be virtually impossible for a pharmacist to add the microscopic amount which would be involved in the average prescription. Further, such products as tablets can be prepared in special ways in a factory, such as being made so that they will dissolve very slowly. It would be impractical to do this in the ordinary pharmacy. Undoubtedly, a contributing reason is an increasing use of trade names for particular combinations of ethical drugs. Here the situation is parallel to that in the proprietary medicine field. The manufacturer tries to persuade doctors that its particular combination of ethical drugs under trade name "X" is superior to all other products used for the same purpose, just as the manufacturer of Anacin or Bufferin tries to persuade the general public that its product is superior to all other similar products.

CHAPTER VI

MANUFACTURERS AND DISTRIBUTORS AT THE MANUFACTURING LEVEL

106. Drugs are sold to the public in dosage forms. This means that there are at least two stages in the manufacture of drugs. First, there is the manufacture of the basic drug itself and then there is the preparation of the dosage form. In some instances, there is a third step because a firm may buy dosage forms, say tablets or capsules, in quantities of many thousands and then package them in tens, fifties, one hundreds, etc., for resale. Because the various steps in the manufacture of the basic drug and the preparation of the package of the drug (either alone or in combination with other drugs) which is sold in a drug store are frequently performed by different firms, there is a wide variety of suppliers of drugs.

107. There is another important factor in the situation. Certain drugs are controlled by patents held by one or a small number of firms. In such cases, these firms normally control the manufacture and sale of the drugs in question and do not allow other firms to deal in them. On the other hand, certain other drugs are either not patented or, for one reason or another, licences under any patents which do exist are granted freely. Trade in these drugs is free in the sense that any firm can obtain these drugs freely. Also, in practice, any drug supplier can usually obtain dosage forms of these drugs. For example, a small drug manufacturer whose limited facilities could only handle simple and standard drugs can add various dosage forms of the older penicillins to his line by buying them already prepared and putting his own label on them. In contrast, it would be impossible for such a manufacturer to obtain dosage forms of penicillin V (except by importing them, as explained elsewhere in this Statement).

108. In Canada, there is still another aspect to the situation. Many firms are branches or subsidiaries of foreign firms. While many of these firms carry a broad line of drugs, each tends, quite naturally, to concentrate on any specialties which the parent firm has developed. Since such products are identical with those of the parent firm, the branch or subsidiary may simply bring in the prepared dosage forms, sometimes in bulk and sometimes already packaged, rather than set up separate manufacturing facilities in Canada. The practice varies from firm to firm and even within

the same firm in respect of different drugs. Thus, even the largest drug firms in Canada which manufacture on a substantial scale are, in respect of certain products, simply resellers of dosage forms of those products which are imported.

109. In general terms, the principal types of firms in the ethical drug field are as follows:

(a) Manufacturers of basic drugs. Some firms, of which Fine Chemicals of Canada Limited is an example, simply manufacture basic drugs and sell these drugs in bulk to other firms. Also, U.S. and European firms which simply manufacture basic drugs maintain sales agencies in Canada. The large ethical drug firms mentioned in the next paragraph also manufacture basic drugs and some sell certain of these drugs in bulk form and in prepared dosage forms, in bulk quantities, to other manufacturers and distributors. They also, of course, sell prepared dosage forms under their own labels through their own sales organizations to the trade and public.

(b) Large ethical drug houses. These firms specialize in ethical drugs, although they may carry a few proprietary drug lines. In some cases, one firm will operate in the ethical drug field while a related firm will operate in the proprietary medicine and sundry field. Thus, Bristol Laboratories of Canada, Ltd. is a related company to Bristol-Myers Company and Riker Pharmaceutical Company, Limited is the ethical drug firm of the Rexall Drug group. The principal characteristics of the large ethical drug firms are that they have the facilities to manufacture and prepare complicated drugs and dosage forms of these drugs, that they carry on research, that they are able to develop company specialties either by developing new drugs or by developing combinations which have or are claimed to have unique properties, and that they are able to carry out promotional activities on a scale that ensures that their products are known and recognized by the medical and pharmacal professions. These firms have established reputations, which appear to be fully deserved, for high-quality products. Much of the research, development of specialty products and quality control exercised in the preparation of products is carried on outside Canada.

(c) Small ethical drug houses. These vary widely in size but seem to be generally differentiated from the large ethical drug houses not only on the basis of size or volume of business, but also because they do not deal in the newer and more complex drugs (unless they merely purchase such drugs for resale); they carry on little or no research, they are not able to develop new drugs or important specialties and they are unable to carry on elaborate promotional campaigns. The products which they do sell may be of high quality, indeed some have usually been purchased from the large ethical drug houses and are identical with those sold by the latter, but the small firms do not enjoy the same reputation as the large firms.

(d) Specialty firms in the ethical drug field. Some firms are small in terms of volume of business because they specialize in a particular field of drugs but, within that field, their products are generally recognized as being among the best available. An example is Baxter Laboratories of Canada, Limited which specializes in parenteral solutions and related products. (Baxter Laboratories of Canada, Limited is a wholly-owned subsidiary of Baxter Laboratories, Inc., Illinois.)

(e) Custom manufacturers and packagers. Some firms are custom manufacturers or packagers. They either buy or are supplied with the basic drugs and prepare dosage forms and package them for other firms. They do not, themselves, sell directly to the trade or the public. The information supplied to the Director indicates that the number of these

firms is increasing, apparently as small manufacturers and distributors wish to add products made to their orders and specifications to their lines.

(f) Certain firms whose main business is in related fields are important distributors of drugs. Ingram & Bell Limited, for example, does the bulk of its business in surgical supplies and hospital equipment, but also does a large business in drugs. It sells drug products which it manufactures or has manufactured to its specifications and acts as the national distributor for certain other manufacturers.

(g) Many foreign firms do not have branches or subsidiaries in Canada, but are represented by agents in Canada. These firms usually have a limited line of products and do only a relatively small amount of business in Canada. In these cases, the drug products come into Canada packaged and ready for resale.

110. In the proprietary, medicine, household remedy and sundry drug products field the situation is somewhat different. A few firms manufacture and sell a wide line of products. The Rexall Drug Company Limited is an example. The majority of firms in this field concentrate on a few products. The names of many of these have become household words because of long-continued advertising. National distributors which handle the products of several manufacturers are quite common. Just as the ethical drug firms manufacture a few proprietary drugs, so the proprietary firms manufacture a few ethical drug products. However, it is much more usual for proprietary drug firms to manufacture toiletries and similar lines along with proprietary drugs. Wholesale drugs firms, whose main business is distributing the products of other manufacturers, usually package and sell a limited line of the commoner proprietary drugs and household remedies under their own labels.

111. There is a very wide variety in the size of firms in the proprietary medicine, household remedy and sundry drug field. Various persons in the trade, such as officers of wholesale firms, stated that, in their experience, sales of proprietary medicines have declined over the years in relation to sales of ethical drugs. Moreover, the bulk of the sales of proprietary medicines now are of a relatively few, well-established products, while many products which were at one time fairly widely used as family remedies are being sold in smaller and smaller quantities. The D.B.S. publication, "The Medicinal and Pharmaceutical Preparations Industry" gives the following sales figures for two selected years:

	<u>1951</u>	<u>1957</u>
	\$	\$
Total sales	89,248,867	140,092,919
Proprietary medicines	16,248,750	22,325,936

It will be noted that while sales of proprietary medicines increased, the percentage of total drug sales accounted for by such sales decreased from 18.2 per cent to 15.9 per cent.

112. Foreign firms are very important in the drug field in Canada. Some foreign firms simply operate branches in Canada, but the great majority operate subsidiary Canadian companies. In some cases, the relationship is more complex than that of simple parent and subsidiary company, there may be other intermediate companies, holding companies or common ownership of stock involved. To avoid repetitious detail, where the information indicates that control of a Canadian company is exercised either directly or indirectly by a foreign company, the Canadian company is referred to as a subsidiary. The importance of branches and subsidiaries of foreign companies in the drug field in Canada can be gathered from Appendix I. The following list shows the situation with respect to the companies which reported the largest sales of ethical drugs:

<u>Company Operating in Canada</u>	<u>Name of Parent or Controlling Company where Applicable</u>
Abbott Laboratories Limited	Abbott Laboratories, Illinois, U.S.A.
Ayerst, McKenna & Harrison Limited	American Home Products Corporation, New York, U.S.A.
Bristol Laboratories of Canada Limited	Bristol-Myers Company, New York, U.S.A.
The British Drug Houses (Canada) Ltd.	The British Drug Houses Limited, London, England.
Burroughs Wellcome & Co. (Canada) Ltd.	The Wellcome Foundation Ltd., London, England.
Ciba Company Limited	Ciba Limited, Basle, Switzerland.
Cyanamid of Canada Limited	American Cyanamid Company, New York, U.S.A.
Charles E. Frosst & Co.	Not a subsidiary.
Geigy Pharmaceuticals, Division of Geigy (Canada) Limited	J. R. Geigy S.A., Basle, Switzerland.
Glaxo (Canada) Ltd.	Glaxo Laboratories Limited, Middlesex, England.
Glaxo-Allenburys (Canada) Limited	
Hoffmann-La Roche Limited	Hoffmann-La Roche Incorporated, New Jersey, U.S.A. (Related to F. Hoffmann-La Roche & Co. Ltd., Basle, Switzerland.)

<u>Company Operating in Canada</u>	<u>Name of Parent or Controlling Company where Applicable</u>
Frank W. Horner Limited	Not a subsidiary.
Eli Lilly and Company (Canada) Limited	Eli Lilly and Company, Indiana, U.S.A.
Merck & Co. Limited	Merck & Co., Inc., New Jersey, U.S.A.
Parke, Davis & Company, Ltd.	Branch of Parke, Davis & Company, Ltd., Nevada, U.S.A. Company is a subsidiary of Parke, Davis & Company, Michigan, U.S.A.
Pfizer Canada	Division of Pfizer Corporation, Panama, which is a subsidiary of Chas. Pfizer & Co., Inc., New York, U.S.A.
Pitman-Moore of Canada Limited	Allied Laboratories Inc., Missouri, U.S.A.
Poulenc Limitée	Société des Usines Chimiques Rhône-Poulenc, Paris, France.
Rougier Inc.	Partly owned by La Compagnie Pharmaceutique Rameau Limitée, Montreal. No further particulars known.
Schering Corporation Limited	Schering Corporation, New Jersey, U.S.A.
G. D. Searle & Co. of Canada Limited	G. D. Searle & Co., Illinois, U.S.A.
Smith Kline & French Inter-American Corporation	Branch of Smith Kline & French Inter-American Corporation, Pennsylvania, which is a subsidiary of Smith Kline & French Laboratories, Pennsylvania, U.S.A.
E. R. Squibb & Sons of Canada Limited	Subsidiary of E. R. Squibb & Sons, New York which is a division of Olin Mathieson Chemical Corporation, New York.
The Upjohn Company of Canada	Branch of Upjohn International Operations, Inc. which is a subsidiary of The Upjohn Company, both of Michigan, U.S.A.
Warner-Chilcott Laboratories Co. Limited	Subsidiary of Warner-Lambert Canada Limited which is a subsidiary of Warner-Lambert Pharmacal Company, New Jersey, U.S.A.
Winthrop Laboratories of Canada Ltd.	Sterling Drug Inc., New York, U.S.A.
John Wyeth & Brother (Canada) Ltd.	American Home Products Corporation, New York, U.S.A.

CHAPTER VII

RETAIL PHARMACIES

113. There have been notable increases in the number of pharmacies operating in Canada and the value of sales by pharmacies over the last thirty years. These increases are reflections of the increase in population and, more important, the increasing use of drugs to treat physical and psychological disorders.

114. The following figures give an indication of the scale of the increases:

<u>Item</u>	<u>1930</u>	<u>1941</u>	<u>1951</u>	<u>Per Cent Increase</u>		
				<u>1930- 1941</u>	<u>1941- 1951</u>	<u>1930- 1951</u>
Number of Pharmacies	3,559	3,956	4,325	11.2	9.3	21.5
Value of sales by Pharmacies (\$'000)	\$76,848.9	\$101,027.4	\$248,448.8	31.5	145.9	223.3

Source: Census of Canada, 1951, Retail Trade,
Volume VII, Table 6.

115. The trend to an increasing number of pharmacies has continued since 1951. The following table gives an estimate of the number of pharmacies in Canada for each year from 1951 to 1960 inclusive:

TABLE III

PHARMACIES IN CANADA, 1951-60

<u>Year</u>	<u>Number of Pharmacies</u>
1951	4,098
1952	4,094
1953	4,465
1954	4,457
1955	4,638
1956	4,663
1957	4,733
1958	4,773
1959	4,801
1960	4,915

Source: National Health and Welfare Department,
Division of Narcotic Control.

Note: The figures for 1951 and 1952 are estimated from the figures for 1953. The figures do not include approximately 100 doctors in the Province of Quebec who operate dispensaries in connection with their practices, nor approximately 100 registered pharmacies which do not deal in narcotics.

This table shows that the per cent increase in the number of licensed pharmacies from 1951 to 1960 was 19.9 per cent, almost as much as the increase from 1930 to 1951.

116. Using the Dominion Bureau of Statistics population figures and

the preceding figures of the number of licensed pharmacies, it is possible to calculate the ratio of population to pharmacies in Canada. These figures indicate that there was an overall increase in the number of persons being served by each pharmacy in the order of 12.6 per cent from 1930 to 1951 and of 6.0 per cent from 1951 to 1960:

TABLE IV
AVERAGE NUMBER OF PERSONS PER PHARMACY

<u>Year</u>	<u>Census*</u>	<u>Health and Welfare**</u>
1930	2,860	
1941	2,909	
1951	3,239	3,418
1952		3,532
1953		3,325
1954		3,430
1955		3,385
1956		3,449
1957		3,505
1958		3,572
1959		3,633
1960		3,624

* Number of pharmacies as recorded by Census of Canada, 1951, Retail Trade, Volume VII, Table 6.

** Number of pharmacies as recorded by National Health and Welfare Department, Division of Narcotic Control.

Note: Population statistics were obtained from Population of Canada by Provinces, Estimated for Intercensal Years and are as of June 1 of each year.

117. Sales by drug stores (this includes drug stores with and without soda fountains) for the years 1951 to 1959 inclusive are given below:

TABLE V
ESTIMATED RETAIL TRADE OF DRUG STORES IN CANADA

<u>Year</u>	<u>All Stores</u> <u>(\$'000)</u>	<u>Chain Stores</u> <u>(\$'000)</u>	<u>Independent</u> <u>Stores</u> <u>(\$'000)</u>
1951	231,816	31,019	200,797
1952	267,067	33,504	233,563
1953	282,219	34,805	247,414
1954	281,810	35,908	245,901
1955	300,341	36,660	263,681
1956	329,028	41,299	287,730
1957	357,579	45,437	312,143
1958	362,731	49,912	332,819
1959	404,268	53,264	351,004

Sources: D.B.S., Retail Trade, 1951 to 1958.

D.B.S., Retail Trade, Monthly Estimated Retail Trade, December 1959.

These figures indicate that retail sales by drug stores have increased by approximately 62 per cent from 1951 to 1959 which shows a much smaller rate of increase than the phenomenal growth from 1941 to 1951.

118. The operating results of drug stores are given in Tables VI and VII. It is interesting to note the position that the operating results of independent drug stores hold relative to the operating results of other types of independent stores. Table VIII gives such a comparison for all independent stores for which data are available^x for 1956. The figures in brackets indicate the relative position of independent drug stores. For unincorporated stores, the gross profit and net profit relative to net sales of drug stores were exceeded only by those of jewellery stores. Operating expenses as a per cent of net sales for drug stores were lower than those in women's clothing stores, family shoe stores, appliance, radio and television stores and jewellery stores. For incorporated stores, gross profits relative to net sales were higher in both jewellery and family shoe stores than in drug stores; operating expenses were higher in women's clothing stores, family shoe stores and jewellery stores; and net profits were higher in jewellery stores.

^x Restaurants, filling stations, garages, grocery stores and general stores are not classed in the D.B.S. figures as unincorporated and incorporated and therefore were not included.

TABLE VI

OPERATING RESULTS OF INDEPENDENT DRUG STORES AND BALANCE SHEET
RATIOS (AS AT DECEMBER 31) 1950, 1952, 1954 AND 1956

I t e m	U n i n c o r p o r a t e d			I n c o r p o r a t e d			
	1950	1952	1954	(P e r C e n t o f N e t S a l e s)			
				1950	1952	1954	1956
Gross profit	28.94	28.94	29.82	30.26	33.40	32.14	32.76
Operating expenses:							
Employees' salaries	8.52	8.68	9.20	8.62	18.48	18.53	18.37
Occupancy	4.58	4.32	4.77	5.19	5.77	5.16	5.13
Office and store supplies	0.58	0.59	0.62	0.56	0.66	0.64	0.57
Advertising	0.79	0.74	0.83	0.80	1.18	1.08	0.98
All other expenses	2.57	2.66	2.81	2.97	2.86	3.09	3.25
Total Operating Expenses	17.04	16.99	18.23	18.14	28.95	28.50	28.30
Net operating profit before deduction of income tax*	11.90	11.95	11.59	12.12	4.45	3.64	4.46
Current ratio	4.13 3.87	3.97 3.68	3.52 4.36	4.20 3.78	4.36 3.73	3.98 3.32	4.04 3.50
Liquidity ratio		1.36 1.32	1.06 1.48	1.47 1.09	-	1.46 1.13	1.51 1.18
Working capital to net worth ratio	0.56 0.78	0.58 0.76	0.53 0.78	0.53 0.74	0.66 0.80	0.63 0.78	0.63 0.79
Worth debt ratio	2.94 2.70	3.13 2.68	3.04 2.91	3.05 2.17	2.63 2.38	2.09 2.00	2.27 2.15
Turnover of total capital employed		1.90 2.64	1.91 2.60	1.76 2.76	-	1.49 2.41	1.82 2.52

*Proprietors' salaries included for unincorporated stores.

**Owned.

***Rented.

Source: D.B.S. Operating Results and Financial Structure, Independent Drug Stores, 1952, 1954, 1956.

Note: The operating result ratios are "weighted" according to the 1951 Census weights of the different sales sizes for independent stores.

TABLE VII

OPERATING RESULTS OF CHAIN DRUG STORES, 1951, 1953, 1955, 1957 AND 1959*

	Chain Drug Stores					Incorporated Chain Drug Stores				
	<u>1951</u>	<u>1953</u>	<u>1955</u>	<u>1957</u>	<u>1959</u>	<u>1951</u>	<u>1953</u>	<u>1955</u>	<u>1957</u>	<u>1959</u>
Gross profit	33.74	33.78	34.93	34.36	33.92		34.20	35.36	34.76	34.26
Operating expenses :										
Salaries	18.03	18.34	19.07	18.76	18.51					
Occupancy	4.98	5.09	5.05	5.03	5.34					
Advertising	1.13	1.13	0.99	1.09	1.24					
All others	6.39	6.04	6.56	6.48	6.47					
Total operating expenses	30.53	30.60	31.67	31.36	31.56		31.16	32.26	31.69	32.02
Net operating profit	3.21	3.18	3.26	3.00	2.36		3.04	3.10	3.07	2.24

*All figures expressed as per cent of net sales.

Source: D.B.S. Operating Results of Chain Drug Stores, 1953, 1955, 1957 and 1959.

TABLE VIII
OPERATING RESULTS OF INDEPENDENT RETAIL
STORES - 1956

	<u>Gross Profit</u>	<u>Operating Expenses</u>	<u>Net Operating Profit*</u>
	(Per Cent of Net Sales)		
Men's Clothing Stores			
Unincorporated	28.17 (5)	17.31 (8)	10.86 (4)
Incorporated	30.76 (5)	27.14 (5)	3.62 (3)
Women's Clothing Stores			
Unincorporated	28.29 (4)	19.56 (2)	8.73 (7)
Incorporated (rented stores only)	31.78 (4)	28.61 (3)	3.17 (5)
Family Clothing Stores			
Unincorporated	26.54 (6)	17.52 (7)	9.02 (6)
Incorporated	30.32 (6)	27.05 (6)	3.27 (4)
Family Shoe Stores			
Unincorporated	29.43 (3)	18.18 (4)	11.25 (3)
Incorporated (rented stores only)	33.49 (2)	30.40 (2)	3.09 (6)
Drug Stores			
Unincorporated	30.26 (2)	18.14 (5)	12.12 (2)
Incorporated	32.76 (3)	28.30 (4)	4.46 (2)
Fuel Dealers			
Unincorporated	21.12 (10)	15.69 (10)	5.43 (10)
Incorporated	22.13 (10)	19.75 (10)	2.38 (8)
Hardware Stores			
Unincorporated	25.79 (8)	16.43 (9)	9.36 (5)
Incorporated	26.92 (8)	23.84 (8)	3.08 (7)
Furniture Stores			
Unincorporated	26.08 (7)	17.79 (6)	8.29 (8)
Incorporated	27.95 (7)	25.58 (7)	2.37 (9)
Appliance, Radio and TV Stores			
Unincorporated	25.62 (9)	18.27 (3)	7.35 (9)
Incorporated (rented stores only)	25.50 (9)	23.22 (9)	2.28 (10)
Jewellery Stores			
Unincorporated	40.83 (1)	24.85 (1)	15.98 (1)
Incorporated (rented stores only)	44.23 (1)	39.13 (1)	5.10 (1)

*Before income tax. Proprietors' salaries included
for unincorporated stores.

Source: D.B.S., Operating Results and Financial
Structure Reports on the various types of
stores specified.

119. Drug stores sell many commodities other than prescription drugs. The proportions of total sales that each type of commodity sold by drug stores with and without soda fountains represents are given for 1951 in the following table. It should be noted that approximately 12 per cent of all drug stores operate soda fountains and that approximately 16 per cent of total sales by all drug stores are made by drug stores operating soda fountains.*

TABLE IX
DRUG STORE SALES BY TYPE OF COMMODITY, 1951

<u>I t e m</u>	Drug Stores Without Soda Fountains	Drug Stores With Soda Fountains
	<u>%</u>	<u>%</u>
Sales of all commodities	100.0	100.0
Candy and confectionery	3.1	3.4
Paper goods, stationery and books	3.2	2.7
Cigars, cigarettes and tobacco	8.1	11.6
Drugs and drug sundries, total	81.2	58.3
Prescriptions	19.5	11.4
Drugs, pharmaceuticals, patent medicines and compounds	37.7	28.0
Drug sundries, rubber goods, sick room supplies, etc.	6.9	4.3
Toilet preparations and cosmetics	14.6	13.1
Toilet articles	2.5	1.5
Cameras and photographic equipment	2.0	1.4
Household supplies, total	0.3	0.2
Soaps and cleaning compounds	0.2	0.1
All other household supplies	0.1	0.1
Professional and scientific appliances, instruments and equipment	0.3	-
Miscellaneous merchandise	1.0	1.1
Receipts from the sale of meals and lunches	0.8	21.3

Source: D.B.S., Census of Canada, 1951, Volume VII, Table 20.

120. There have been indications that the proportion of total sales of drug stores represented by prescriptions has been increasing in the last decade as chemotherapy became more successful. The following table gives an estimate of the number of prescriptions, the value of prescriptions filled, the average price of a prescription and the proportion of total sales which are prescription sales:

*D.B.S., Census of Canada, 1951, Volume VII, Table 13.

TABLE X
SALES ON PRESCRIPTION, 1951-59

<u>Year</u>	<u>Number of Prescriptions</u>	<u>Value of Prescriptions</u> \$	<u>Average Price of a Prescription</u> \$	<u>Prescription Sales as % of Total Sales of Drug Stores*</u> %
1951	30,958,675	52,010,574	1.68	15.06
1952	31,453,240	57,244,896	1.82	18.22
1953	31,798,456	64,277,248	2.07	16.30
1954	30,115,818	68,664,067	2.28	19.79
1955	32,908,185	74,372,498	2.26	19.56
1956	35,102,361	87,404,881	2.49	22.1
1957	40,036,416	103,230,236	2.61	23.7
1958	40,445,325	112,438,004	2.78	23.6
1959	43,916,605	130,871,483	2.98	26.0
% Increase 1959/1951	41.9%	151.6%	77.4%	72.2%

Source: The Canadian Pharmaceutical Association, 18th Annual Survey, Professor H. J. Fuller, Canadian Pharmaceutical Journal, September 1960, p. XVI.

*Compiled from the Canadian Pharmaceutical Journal, Annual Surveys, Numbers 10-18, inclusive.

121. Table XI is a compilation of the average operating results of pharmacies reporting to the Canadian Pharmaceutical Journal annual surveys. It gives in greater detail the expenses of operating a pharmacy and gives proprietors' salaries as well as net operating profit. This gives some indication of the total return to the pharmacist both as salary and as return on investment.

TABLE II

OPERATING RESULTS OF PHARMACIES REPORTING
PRESCRIPTION SALES IN CANADA, 1951-59

	1951 ^M	1952 ^M	1953	1954	1955	1956	1957	1958	1959
No. of Pharmacies Reporting	149	250	165	272	244	307	293	331	315
Sales	\$50,852 - 100.0%	\$53,601 - 100.0%	\$50,850 - 100.0%	\$79,431 - 100.0%	\$50,840 - 100.0%	\$54,664 - 100.0%	\$94,865 - 100.0%	\$103,110 - 100.0%	\$106,532 - 100.0%
Cost of Goods Sold	42,654 - 70.1%	44,756 - 70.4%	45,430 - 69.5%	54,167 - 68.3%	54,358 - 69.5%	57,233 - 67.6%	65,560 - 67.0%	69,187 - 67.1%	70,751 - 66.4%
Gross Margin	18,198 - 23.5%	18,845 - 29.3%	25,430 - 31.5%	25,164 - 31.7%	25,864 - 32.0%	27,431 - 32.4%	31,305 - 33.0%	33,923 - 32.9%	35,801 - 33.5%
EXPENSES									
Proprietor's or Manager's Salary	\$ 3,652 - 5.0%	\$ 4,261 - 6.7%	\$ 5,725 - 7.1%	\$ 6,029 - 7.6%	\$ 6,467 - 8.0%	\$ 7,027 - 8.3%	\$ 7,400 - 7.8%	\$ 8,249 - 8.0%	\$ 8,631 - 8.1%
Employees' Wages	5,173 - 8.5%	4,859 - 7.6%	7,537 - 9.8%	7,679 - 9.7%	8,375 - 10.4%	8,720 - 10.3%	9,866 - 10.4%	10,621 - 10.3%	10,975 - 10.3%
Rent	1,359 - 2.6%	1,406 - 2.7%	1,940 - 2.4%	2,039 - 2.6%	2,126 - 2.6%	2,117 - 2.5%	2,277 - 2.4%	2,578 - 2.5%	2,664 - 2.5%
Advertising	509 - 1.0%	540 - 0.9%	1,003 - 1.2%	920 - 1.2%	922 - 1.1%	931 - 1.1%	1,044 - 1.1%	1,134 - 1.1%	1,172 - 1.1%
Delivery	304 - 0.5%	337 - 0.5%	559 - 0.6%	516 - 0.6%	555 - 0.7%	677 - 0.6%	664 - 0.7%	825 - 0.6%	746 - 0.7%
Depreciation on Fixtures and Equipment	426 - 0.7%	572 - 0.9%	744 - 0.9%	746 - 0.9%	719 - 0.9%	847 - 1.0%	949 - 1.0%	1,134 - 1.1%	1,278 - 1.2%
Heat, Light, Power	426 - 0.7%	445 - 0.7%	574 - 0.7%	524 - 0.7%	531 - 0.8%	677 - 0.8%	664 - 0.7%	722 - 0.7%	746 - 0.7%
Taxes	183 - 0.3%	216 - 0.3%	235 - 0.3%	294 - 0.4%	283 - 0.4%	254 - 0.3%	379 - 0.4%	309 - 0.3%	426 - 0.4%
Insurance	243 - 0.4%	293 - 0.5%	291 - 0.4%	333 - 0.4%	348 - 0.4%	339 - 0.4%	379 - 0.4%	412 - 0.4%	456 - 0.4%
Interest	183 - 0.3%	172 - 0.3%	146 - 0.2%	246 - 0.3%	218 - 0.3%	339 - 0.4%	379 - 0.4%	412 - 0.4%	533 - 0.5%
Repairs	243 - 0.4%	222 - 0.4%	332 - 0.4%	325 - 0.4%	396 - 0.5%	423 - 0.5%	474 - 0.5%	516 - 0.5%	533 - 0.5%
Telephone	183 - 0.3%	172 - 0.3%	226 - 0.3%	246 - 0.3%	234 - 0.3%	254 - 0.3%	285 - 0.3%	309 - 0.3%	320 - 0.3%
Bad Debts	60 - 0.1%	52 - 0.1%	80 - 0.1%	95 - 0.1%	97 - 0.1%	85 - 0.1%	103 - 0.1%	106 - 0.1%	106 - 0.1%
Miscellaneous	1,400 - 2.3%	967 - 1.5%	1,674 - 2.1%	1,785 - 2.3%	1,593 - 2.0%	1,355 - 1.6%	1,208 - 1.6%	1,856 - 1.6%	2,024 - 1.9%
Total Expenses	\$14,424 - 23.7%	\$14,514 - 22.8%	\$21,435 - 26.5%	\$21,777 - 27.5%	\$22,954 - 28.4%	\$24,045 - 28.4%	\$26,657 - 28.1%	\$29,180 - 28.3%	\$30,560 - 28.7%
Net Operating Profit	\$ 3,774 - 6.2%	\$ 4,331 - 6.8%	\$ 3,994 - 4.9%	\$ 3,397 - 4.3%	\$ 2,950 - 5.6%	\$ 3,366 - 4.0%	\$ 4,648 - 4.9%	\$ 4,743 - 4.6%	\$ 5,821 - 4.9%
Other Income	454	347	408	417	497	499	526	544	635
Proprietor's Salary	3,652	4,261	5,725	6,029	6,467	7,027	7,400	8,249	8,631
Total Income	\$ 7,880	\$ 8,939	\$10,121	\$ 9,833	\$ 9,914	\$10,912	\$12,574	\$13,536	\$14,477
Value of Merchandise Stock	\$12,160	\$11,977	\$13,478	\$15,378	\$15,872	\$15,977	\$17,499	\$19,580	\$20,221
Annual Rate of Turnover	3.5%	3.7%	3.9%	3.7%	3.7%	3.6%	3.5%	3.6%	3.6%
Average Value of Fixtures	\$ 4,690	\$ 4,490	\$ 4,785	\$ 5,089	\$ 4,266	\$ 5,703	\$ 5,808	\$ 6,210	\$ 6,230
Average Accounts Receivable	\$ 1,110	\$ 1,110	\$ 1,266	\$ 1,975	\$ 2,109	\$ 1,989	\$ 2,305	\$ 2,408	\$ 2,538
Average Accounts Payable	\$ 3,056	\$ 3,056	\$ 2,605	\$ 3,755	\$ 4,215	\$ 4,293	\$ 4,852	\$ 4,666	\$ 5,126
Average Price Per Rx	\$ 1.68	\$ 1.82	\$ 2.07	\$ 2.28	\$ 2.26	\$ 2.49	\$ 2.61	\$ 2.78	\$ 2.98
Average Price Per New Rx	\$ 1.84	\$ 1.79	\$ 2.04	\$ 2.09	\$ 2.27	\$ 2.59	\$ 2.65	\$ 2.98	\$ 3.00
Average Price Per Repeat Rx	\$ 1.57	\$ 1.66	\$ 1.86	\$ 1.93	\$ 2.00	\$ 2.39	\$ 2.55	\$ 2.67	\$ 2.86
Average No. of Rx	5,390	6,118	6,401	6,668	7,141	7,566	8,596	8,770	9,384
Average No. of New Rx			4,475	4,036	3,802	4,229	5,084	5,140	5,547
Average No. of Repeat Rx			2,668	2,566	2,430	2,790	3,065	3,533	3,472
Average Sales of Rx	\$ 9,036 ^M	\$11,135 ^M	\$13,325	\$15,700	\$16,139	\$18,789	\$22,499	\$24,325	\$27,732
Average Sales of New Rx			\$ 8,562	\$ 8,615	\$ 8,615	\$10,970	\$13,494	\$15,353	\$16,684
Average Sales of Repeat Rx			\$ 4,641	\$ 4,938	\$ 4,861	\$ 6,663	\$ 7,856	\$ 8,926	\$ 9,953
Ratio of Rx Sales to Total Sales	15.06%	18.25%	18.32%	19.79%	19.96%	22.1%	23.7%	23.6%	26.0%

^MAverages refer to all pharmacies and not only to those pharmacies reporting prescription sales.

^MEstimates; average number of prescriptions multiplied by average price per prescription.

122. Table XII is a breakdown of operating results of pharmacies reporting in 1959, according to the per cent of total sales made up of sales of prescriptions. While the average sales of those pharmacies reporting prescription sales as ten per cent to twenty per cent of total sales were substantially higher than those reporting prescription receipts over forty per cent of total sales, there was a decrease in total expenses as prescription sales increased sufficient to make the total income of the pharmacies selling a higher proportion of prescriptions greater than that of pharmacies selling an average of fewer prescriptions.

AVERAGE COST AND PROFITS OF PHARMACIES
REPORTING PRESCRIPTION SALES, 1959

TABLE XII

	All Pharmacies Reporting Receipts	Pharmacies with Rx Receipts 10% to 20% of Total Receipts	Pharmacies with Rx Receipts 20% to 30% of Total Receipts	Pharmacies with Rx Receipts 30% to 40% of Total Receipts	Pharmacies with Rx Receipts Over 40% of Total Receipts
Number of Pharmacies Reporting	316	116	103	63	35
Sales	\$106,582 - 100.0%	\$121,900 - 100.0%	\$95,945 - 100.0%	\$102,420 - 100.0%	\$99,629 - 100.0%
Cost of Goods Sold	70,751 - 66.4%	82,892 - 68.0%	65,413 - 67.5%	66,163 - 64.6%	60,674 - 60.9%
Gross Margin	35,831 - 33.6%	39,008 - 32.0%	30,532 - 32.5%	36,257 - 35.4%	38,955 - 39.1%
EXPENSES					
Proprietor's or Manager's Salary	\$ 8,631 - 8.1%	\$ 8,777 - 7.2%	\$ 7,797 - 8.3%	\$ 8,398 - 8.2%	\$10,162 - 10.2%
Employees' Wages	10,975 - 10.3%	13,653 - 11.2%	8,643 - 9.2%	10,447 - 10.2%	10,959 - 11.0%
Rent	2,684 - 2.5%	3,413 - 2.8%	2,161 - 2.3%	2,356 - 2.3%	2,690 - 2.7%
Advertising	1,172 - 1.1%	1,463 - 1.2%	939 - 1.0%	1,229 - 1.2%	1,096 - 1.1%
Delivery	1,446 - 0.7%	853 - 0.7%	688 - 0.7%	819 - 0.8%	897 - 0.9%
Depreciation on Fixtures and Equipment	1,278 - 1.2%	1,341 - 1.1%	1,127 - 1.2%	1,332 - 1.3%	996 - 1.0%
Heat, Light, Power	74 - 0.7%	1,097 - 0.9%	688 - 0.7%	615 - 0.6%	399 - 0.4%
Taxes	436 - 0.4%	356 - 0.3%	376 - 0.4%	410 - 0.4%	299 - 0.3%
Insurance	436 - 0.4%	356 - 0.3%	376 - 0.4%	410 - 0.4%	299 - 0.3%
Interest	533 - 0.5%	731 - 0.6%	583 - 0.6%	512 - 0.5%	399 - 0.4%
Repairs	330 - 0.3%	376 - 0.4%	376 - 0.4%	410 - 0.4%	199 - 0.2%
Telephone	106 - 0.1%	356 - 0.3%	282 - 0.3%	307 - 0.3%	399 - 0.4%
Bad Debts	106 - 0.1%	122 - 0.1%	94 - 0.1%	102 - 0.1%	99 - 0.1%
Miscellaneous	2,034 - 1.9%	2,072 - 1.7%	1,973 - 2.1%	2,048 - 2.0%	2,192 - 2.2%
Total Expenses	\$30,580 - 28.7%	\$35,351 - 29.0%	\$26,023 - 27.7%	\$29,395 - 28.7%	\$30,985 - 31.1%
Net Profit	\$ 5,221 - 4.9%	\$ 3,657 - 3.0%	\$ 4,509 - 4.8%	\$ 6,862 - 6.7%	\$ 7,970 - 8.0%
Other Income	685	995	457	467	261
Proprietor's Salary	8,631	8,777	7,797	8,398	10,162
Total Income ^a	\$14,477 (\$13,211)	\$13,412 (\$12,103)	\$12,743 (\$12,380)	\$15,727 (\$15,303)	\$18,383 (\$15,801)
Value of Merchandise Stock	\$20,221	\$21,956	\$19,060	\$20,941	\$16,853
Annual Rate of Turnover	3.6%	3.6%	3.5%	3.5%	3.5%
Average Value of Fixtures	\$ 6,230	\$ 7,461	\$ 5,354	\$ 6,667	\$ 4,778
Average Accounts Receivable	\$ 2,538	\$ 2,457	\$ 2,161	\$ 3,299	\$ 2,335
Average Accounts Payable	\$ 5,125	\$ 4,055	\$ 6,019	\$ 6,253	\$ 4,592
Average Price per Rx	\$ 2.98	\$ 3.12	\$ 2.97	\$ 2.91	\$ 2.90
Average Price per New Rx	\$ 3.00	\$ 3.18	\$ 2.92	\$ 2.83	\$ 2.96
Average Price per Repeat Rx	\$ 2.86	\$ 3.17	\$ 2.77	\$ 2.61	\$ 2.69
Average Number of Rx	9,294	6,855	7,954	11,820	17,322
Average Number of New Rx	5,547	4,592	4,977	7,062	9,222
Average Number of Repeat Rx	3,472	2,687	3,034	4,654	6,502
Average Receipts from Rx	\$27,732	\$21,390	\$23,648	\$34,432	\$50,395
Average Receipts from New Rx	\$16,694	\$14,621	\$14,548	\$27,349	\$27,349
Average Receipts from Repeat Rx	\$ 9,953	\$ 8,536	\$ 8,431	\$12,209	\$17,533
Ratio of Rx Receipts to Total Receipts	28.0%	17.5%	25.1%	33.6%	50.5%

^aProfessor Fuller has given two Total Income figures. The first figure is Total Income as calculated by applying to average total sales percentage rate found by averaging the percentage rate of income calculated from figures supplied by reporting pharmacies. The second figure is the average income of the reporting pharmacies (Canadian Pharmaceutical Journal, May 15, 1953, p. 24-332.)

Source: Canadian Pharmaceutical Journal, September 1960, p. XVIII.

123. Professor Fuller has also compiled information concerning the operations of pharmacies in the United States. The following table is a general comparison for 1957 of the situation in Canada and the United States:

TABLE XIII

PHARMACIES - CANADA AND THE UNITED STATES, 1957

	<u>United States</u>	<u>Canada</u>
Number of pharmacies	50,523	4,646
Average number of persons per pharmacy	3,411	3,635
Total sales	\$6,511,000,000	\$437,573,539
Prescription receipts	\$1,643,436,000	\$103,230,236
Number of prescriptions filled	560,899,000	40,036,416
Average price per prescription	\$2.93	\$2.61
Prescription receipts as per cent of total sales	25.2	23.6

Sources: Canadian Pharmaceutical Journal, November 1958,
p. 25-635.
American data obtained from The American Druggist,
January 13, 1958.

124. The table below is taken from the Canadian Pharmaceutical Journal and is a comparison of operating results in 1957 of pharmacies in Canada and in the United States. The Canadian figures are those that appear in Table XI; the American figures are those reported in the Lilly Digest and in the Survey of Operating Costs of Prescription Pharmacies sponsored by the American College of Apothecaries.

COMPARISON OF CANADIAN, LILLY DIGEST, AND AMERICAN COLLEGE OF
APOTHECARIES PHARMACIES REPORTING PRESCRIPTION SALES, 1957

	Canadian Pharmacies	Lilly Digest Survey	American College of Apothecaries
Number of Pharmacies Reporting .	293	1,862	109
Sales	\$94,865 - 100.0%	\$124,584 - 100.0%	\$174,256 - 100.0%
Cost of Goods Sold	53,560 - 57.0%	80,930 - 55.0%	99,152 - 56.9%
Gross Margin	31,305 - 33.0%	43,654 - 35.0%	75,104 - 43.1%
EXPENSES			
Proprietor's or Manager's Salary	\$ 7,400 - 7.8%	\$ 9,688 - 7.8%	\$ 13,940 - 8.0%
Employees' Wages	9,866 - 10.4%	13,989 - 11.2%	32,934 - 18.9%
Rent	2,277 - 2.4%	2,754 - 2.2%	6,448 - 3.7%
Advertising	1,044 - 1.1%	1,718 - 1.4%	2,962 - 1.7%
Delivery	664 - 0.7%	477 - 0.4%	2,440 - 1.4%
Depreciation on Fixtures	949 - 1.0%	1,425 - 1.1%	1,917 - 1.1%
Heat, Light, Power	664 - 0.7%	1,062 - 0.9%	871 - 0.5%
Taxes	379 - 0.4%	1,241 - 1.0%	1,220 - 0.7%
Insurance	379 - 0.4%	634 - 0.5%	
Interest	379 - 0.4%	264 - 0.2%	
Repairs	474 - 0.5%	444 - 0.4%	349 - 0.2%
Telephone	285 - 0.3%	308 - 0.2%	1,220 - 0.7%
Bad Debts	189 - 0.2%	140 - 0.1%	
Miscellaneous	1,708 - 1.8%	2,249 - 1.8%	3,833 - 2.2%
Total Expenses	\$26,657 - 28.1%	\$36,393 - 29.2%	\$68,134 - 39.1%
Net Profit	\$ 4,648 - 4.9%	\$ 7,261 - 5.8%	\$ 6,970 - 4.0%
Other Income	526		
Proprietor's Salary	7,400	9,688	13,940
Total Income	\$12,574	\$16,949	\$20,910
Value of Merchandise Stock	\$17,499	\$20,606	\$28,522
Annual Rate of Turnover	3.5%	3.9%	3.4%
Average Price per Prescription .	\$ 2.61	\$ 2.85	\$ 3.02
Average Number of Prescriptions	8,596	13,502	39,309
Average Receipts from Prescrip- tions	\$22,499	\$38,477	\$113,615
Ratio of Rx Receipts to Total Sales	23.7%	30.9%	65.2%

*Rent, Heat, Light, Power.

Source: Canadian Pharmaceutical Journal, November 1958, p. 26-636.

125. Failures in the retail drug trade are relatively few. The following table gives the failures and relates them to failures in retail trade and total number of drug stores in operation:

TABLE XV
FAILURES* OF DRUG STORES

<u>Year</u>	<u>Number</u>	<u>As Per Cent of Total Retail Failures</u>	<u>As Per Cent of Total Number of Registered Pharmacies</u>
1951	3	.8	.07
1952	8	1.9	.20
1953	7	1.2	.16
1954	10	1.5	.22
1955	10	1.5	.22
1956	7	1.1	.15
1957	6	.8	.13
1958	7	1.0	.15
1959	7	1.0	.15

*Failures include those businesses that ceased operations following assignments of bankruptcy; ceased with loss to creditors after such actions as execution, foreclosure, or attachment; voluntarily withdrew leaving unpaid obligations; were involved in court actions such as receivership, reorganization or arrangement; or voluntarily compromised with creditors out of court.

Sources: Dun & Bradstreet of Canada, Limited, Toronto, Five Important Releases on Canadian Business Failures, 1900-1957, May 26, 1958, and Quarterly Failures Report, April 29, 1960.
National Health and Welfare Department, Division of Narcotic Control.

126. Some concern has been expressed by pharmacists that the number of pharmacists graduating is not keeping pace with the increase in population and the number of retiring pharmacists. In the August 1959 edition of Drug Merchandising, it was said:

" . . .

During the next three years, graduates from the Ontario College of Pharmacy will number less than 75 annually. Yet 125 pharmacists are required each year as normal replacements.

. . ."

(p. 5)

The Dominion Bureau of Statistics reported graduates for the academic years 1949-50 to 1958-59 as follows:

TABLE XVI

GRADUATES IN PHARMACY, 1950-59

<u>Academic Year</u>	<u>Total Graduates</u>	<u>Women Graduates</u>
1949-50	422	65
1950-51	406	46
1951-52	393	40
1952-53	402	53
1953-54	358	32
1954-55	321	42
1955-56	318	51
1956-57	282	54
1957-58	265	42
1958-59	296	53

Sources: D.B.S. Daily Bulletin, March 30,
1960, p. 3.

Information received by phone from D.B.S.

CHAPTER VIII

THE WHOLESALE DRUG TRADE

127. The wholesale drug trade has been expanding as the retail trade in drugs has increased. The following table gives an indication of the expansion from 1941 to 1951:

TABLE XVII

NUMBER AND VALUE OF SALES OF WHOLESALERS OF DRUGS AND DRUG SUNDRIES

	<u>1941</u>	<u>1951</u>	<u>1951/1941</u>
Number of:			
(1) Wholesalers proper	143	141	- 1.4%
(2) Manufacturers' sales branches and offices	8	53	✓ 562.5
(3) Agents and brokers	17	17	-
Total	168	211	✓ 25.6
Sales (\$'000) of:			
(1) Wholesalers proper	43,899.9	76,836.6	✓ 75.0
(2) Manufacturers' sales branches and offices	3,413.1	47,158.7	✓ 1,281.7
(3) Agents and brokers	2,299.8	8,906.6	✓ 287.3
Total	49,612.8	132,901.9	✓ 167.9

Sources: D.B.S., Census of Canada, 1941, Volume XI, Table 3.
D.B.S., Census of Canada, 1951, Volume VIII, Table 3.

The table indicates a substantial increase in both the number of wholesalers and the value of their sales. A notable increase has taken place in the number and particularly in the value of sales of manufacturers' sales branches and offices.

128. Estimates of the wholesale trade in drugs and drug sundries are given below for the years 1951 to 1959 inclusive:

TABLE XVIII

ANNUAL SALES OF DRUG WHOLESALERS, 1951-59

<u>Year</u>	<u>Estimated Annual Wholesale Sales (\$'000,000)</u>
1951	133.3
1952	139.5
1953	147.5
1954	152.5
1955	164.6
1956	176.9
1957	187.7
1958	202.6
1959	219.1*

*Preliminary estimate.

Source: D.B.S., Industry and Merchandising Division, Wholesale Trade, December 1958 and December 1959.

The increase in sales of drug wholesalers from 1951 to 1959 is estimated to be 64.4 per cent, a rate of increase considerably less than that taking place from 1941 to 1951.

129. The operating results of drug wholesalers for the years 1951, 1953, 1955 and 1957 are available. The figures are confined to results of those wholesale merchants performing the full selling, warehousing and delivery functions. Agents, brokers, drop shippers and other specialized types of wholesale distributors are not included. A comparison of the operating results of drug wholesalers with those of other types of wholesalers for 1957 reveals that drug wholesalers' gross and net margins as well as operating expenses are comparatively low being ninth, seventh and ninth respectively in an array of eleven types of wholesalers.

TABLE XIX
OPERATING RESULTS OF DRUG WHOLESALERS

	1951	1953	1955	1957
Number of firms reporting ...	16	22	24	23
Average net sales per firm...	\$2,547,348	\$2,364,354	\$2,974,194	\$4,722,739
		(Per Cent of Net Sales)		
Gross profit	13.43%	12.36%	12.73%	11.79%
Operating expenses -				
Selling	2.18	2.38	1.86	1.75
Warehouse and delivery	2.68	2.61	2.95	3.31
Administrative & general ..	6.09	5.45	5.66	5.28
Total operating expenses	10.95	10.44	10.47	10.34
Net operating profit	2.48	1.92	2.26	1.45
Non-trading income	1.20	1.05	0.89	0.74
Non-trading expenses	0.13	0.16	0.18	0.18
Net profit before income tax deduction	3.55	2.81	2.97	2.01
Stock turnover	5.60	6.68	6.79	8.06

Sources: D.B.S., Industry and Merchandising Division, Operating Results of Drug Wholesalers, 1953, 1955, 1957, and
Operating Results of Miscellaneous Wholesalers, 1951.

TABLE XX

OPERATING RESULTS OF WHOLESALERS IN VARIOUS FIELDS, 1957

<u>Type of Wholesaler</u>	<u>Gross Profit</u>	<u>Operating Expenses</u> (As Per Cent of Sales)	<u>Net Operating Profit</u>
Automotive Parts and Accessories	25.36 (1)	22.10 (1)	3.26 (3)
Drug	11.79 (9)	10.34 (9)	1.45 (7)
Dry Goods	16.04 (6)	14.90 (5)	1.14 (8)
Piece Goods	17.21 (4)	15.54 (3)	1.67 (5)
Footwear	13.60 (7)	12.14 (7)	1.46 (6)
Grocery	6.84 (10)	6.38 (10)	0.46 (10)
Fruit and Vegetable	12.14 (8)	11.29 (8)	0.85 (9)
Tobacco and Confectionery	6.73 (11)	6.38 (10)	0.35 (11)
Hardware	20.05 (2)	16.72 (2)	3.33 (2)
Household Appliance and Electrical Supply ...	18.93 (3)	15.47 (4)	3.46 (1)
Plumbing and Heating Supplies	16.97 (5)	14.04 (6)	2.93 (4)

Source: D.B.S., Industry and Merchandising Division.

130. It is also interesting to note the relative amounts spent by these wholesalers on advertising in 1957:

TABLE XXI

ADVERTISING EXPENDITURES BY WHOLESALERS, 1957

<u>Type of Wholesaler</u>	<u>Advertising (as Per Cent of Sales)</u>
Automotive Parts and Accessories	0.41 (2)
Drug	0.14 (7)
Dry Goods	0.31 (4)
Piece Goods	0.17 (6)
Footwear	0.07 (10)
Grocery	0.09 (8)
Fruit and Vegetable	0.08 (9)
Tobacco and Confectionery	0.06 (11)
Hardware	0.36 (3)
Household Appliance and Electrical Supply	0.54 (1)
Plumbing and Heating Supplies	0.20 (5)

Source: D.B.S., Industry and Merchandising Division.

131. Business failures of drug and chemical wholesalers are relatively low. This information is presented in the following table. It is impossible to determine how many of these failures were of firms distributing drugs exclusively.

TABLE XXII

BUSINESS FAILURES OF DRUG AND CHEMICAL WHOLESALERS, 1951-59

<u>Year</u>	<u>Number</u>	<u>Failures* in Drug and Chemical Wholesale Trade as Per Cent of All Failures in Wholesale Trade</u>
1951	3	4.2
1952	3	4.1
1953	5	5.9
1954	6	4.3
1955	4	3.2
1956	4	3.7
1957	3	2.5
1958	1	.9
1959	6	4.7

*Failures include those businesses that ceased operations following assignments of bankruptcy; ceased with loss to creditors after such actions as execution, foreclosure, or attachment; voluntarily withdrew leaving unpaid obligations; were involved in court actions such as receivership, reorganization or arrangement; or voluntarily compromised with creditors out of court.

Sources: Dun & Bradstreet of Canada, Limited, Toronto, Five Important Releases on Canadian Business Failures, 1900-1957, May 26, 1958, and Quarterly Failures Report, April 29, 1960.

CHAPTER IX

CHANNELS OF DISTRIBUTION AND TRADE AND RETAIL PRICES

132. From the manufacturer's or distributor's level, drugs reach the user through two main channels - hospitals and drug stores. Most hospitals have their own pharmacies and supply the drugs used in the treatment of patients. Apart from drugs so supplied, most ethical drugs are purchased in drug stores. Some drugs are supplied by clinics, doctors, etc., but these are probably insignificant in the overall picture.
133. As will appear, hospitals normally purchase drugs on more favourable terms than do retail druggists. When the retail druggist resells to the customer a markup is taken. If the drug is sold on prescription, the druggist usually adds a prescription fee to the normal retail price. In comparing the final cost of drugs purchased by hospitals and those purchased through retail druggists, it is necessary to consider how the cost to the hospital compares to the cost to the retail druggist, the markup which the druggist takes and, if the drug is a prescription drug, any prescription fee which is included in the price charged the customer.
134. Drugs are sold to hospitals and druggists directly by manufacturers (or distributors at the manufacturing level) and through wholesalers. Direct sales by manufacturers will be considered first.
135. The normal trade discount allowed to both hospitals and retailers is forty per cent off list or suggested resale price. A number of small manufacturers allow fifty per cent off list or suggested resale prices. However, drugs sold to public hospitals are exempt from sales tax which means that hospitals are charged approximately ten per cent less than the retailer. In practice, many drug firms publish a special price list showing net prices to hospitals, while others publish a list showing trade prices less sales tax. These prices would apply on sales to hospitals. (Hospital, except where otherwise indicated, is used to mean a public hospital which can purchase drugs without paying sales tax).
136. Hospitals are sometimes charged prices below the level of list price less forty per cent and less sales tax. These may be special prices regardless of the quantity purchased, or they may be special low prices for purchases of large quantities. Where a special price on purchases of a large quantity is allowed to a hospital, an equivalent price (but with sales tax

added) is usually available to a retailer, but the retailer may not always be able to take advantage of such special price. It may not be practical for a drug store to purchase in the same quantities as a hospital, obviously a mental hospital will require much larger supplies of tranquilizer drugs than a corner drug store. Moreover, the hospital will probably buy in packages of a thousand or even five-thousand tablets, while the druggist must stock packages of twenty-five or fifty tablets which are proportionately more expensive. Certain other drugs or dosage forms of drugs are used chiefly in serious illnesses for which a patient is normally hospitalized. Patients suffering minor illnesses for which they are not hospitalized are not likely to require such drugs and, hence, the druggist will not be called on to fill many prescriptions for them and will only stock small quantities. Thus, although a comparison of prices would appear, at first glance, to indicate that the druggist can buy almost as favourably as a hospital, in fact the hospital may be able to buy on much more favourable terms.

137. In some cases, special low prices which are available to hospitals but not to the trade are established by manufacturers. A rather striking example is afforded by Frosst's Tablet Number 829, reserpine 1 mg., sold under the trade name Alserin. List price is \$11.50 for 100 tablets; \$55.50 for 500 tablets; and \$110.00 for 1,000 tablets. A retailer would pay 60 per cent or \$6.90, \$33.30 and \$66.00 respectively. If a retailer purchased 25,000, the price would be \$46.20 per 1,000 which appears to be the best price available to a retailer. Presumably, the retailer would charge a customer the list price of \$11.50 per 100 plus any prescription fee which might be added. The price of the same tablets to a hospital varies from \$14.00 for 1,000 to \$8.75 per 1,000 on purchases of 50,000 tablets. Thus, while 100 tablets would cost at least \$11.50 if purchased in a drug store on prescription, 100 tablets would cost a hospital no more than \$1.40 and might cost only \$0.87½.

138. Thus, there are several factors which make the prices of drugs purchased through a drug store higher than the prices paid for the same drug by a hospital. First, even for an identical product and package size, the hospital normally pays about 10 per cent less than a retailer. Second, the hospital may buy in larger quantities with resultant discounts. Third, the retailer may have to purchase small packages which are relatively more

expensive than the large sizes purchased by hospitals. Fourth, in the case of some drugs, the dosage forms sold by the retailer are less commonly used and are produced in smaller quantities and are more expensive to manufacture than the dosage forms used in hospitals. Finally (and apart from any extra charge for a prescription which is discussed below), a retailer must take a markup on a price which is already higher than that paid by a hospital.

139. On sales to wholesalers, the policies of different manufacturers vary widely and, although discounts of 40 per cent and 16-2/3 per cent are probably the most common, these are by no means standard. Certain manufacturers, as a matter of policy, sell only to wholesalers and not direct to retailers. At the other extreme, some manufacturers allow only the same discount to wholesalers as they do to retailers which means, of course, that in reselling these products to retailers the wholesalers cannot allow the same discount. From information obtained in informal interviews with officers of various wholesale firms, it would seem that where a manufacturer allows a wholesaler a discount of 40 per cent and 16-2/3 per cent, the wholesaler usually passes on the 40 per cent to the retailer. In other cases, the price to the retailer depends on the discount the wholesaler itself receives. For example, one large firm allows wholesalers a discount of 45 per cent and its catalogue contains the following:

"It is the policy of . . . , in dealing with wholesalers, to sell its products to wholesalers who confine their distribution of . . . products, whether Pr Prescription legend or non-Pr legend, to customers authorized by law to fill or dispense prescriptions. It is suggested that wholesalers serve such customers on the basis of 33-1/3% discount from Catalogue List prices."

140. Information obtained in the informal interviews referred to indicates that the practices of individual druggists in purchasing direct from the manufacturer or through a wholesaler vary widely. A druggist can usually buy more advantageously from a manufacturer but, on the other hand, he is usually required to place an order of a minimum size or, in any event, his savings will not be appreciable unless he does place an order of some size. Hence, where a druggist sells a considerable quantity of a certain product he will tend to buy that product direct from the manufacturer. If he only sells a small quantity of an article, or if he needs the product quickly, he will purchase it from a wholesaler. It appears clear that many

retail druggists rely heavily on wholesalers for supplies and purchase a large proportion of these supplies at a discount somewhat smaller than the forty per cent discount available on direct purchases from the manufacturers. In a very real sense, the wholesaler carries the stock for the retail druggist and this is quite natural in view of the number and variety of drug products a retail druggist may be called upon to supply.

141. In Ontario, one of the large wholesalers, Drug Trading Company Limited, is a co-operative owned by retail druggists. The company grants a rebate to its members (over and above regular discounts), and other wholesalers in the Province have adopted a similar practice in order to remain competitive.

142. Wholesalers normally sell to hospitals at their price to retailers less sales tax. Sales tax on the goods sold to hospitals will have been paid by the wholesalers, but it is then recovered.

143. The discounts just discussed relate to ethical drugs. On proprietary drugs, household remedies and sundry drug products, the situation varies widely, but discounts less than 40 per cent seem to be usual.

144. The foregoing takes no account of "deals" involving special discounts or free goods, usually on condition that a certain quantity is purchased. These are quite common in the drug industry and it is impractical to outline the various types of deals in detail. They vary from firm to firm, from product to product and even with the time of year. Thus, in the autumn or early winter, special deals are frequently offered to encourage dealers to stock and aggressively merchandise vitamins or cold remedies because such products are normally in greater demand during the winter months. Subject to some exceptions, deals are much more commonly offered in connection with proprietary medicines and the commoner ethical drug products. They are not normally offered on sales of the newer and more expensive ethical drugs.

145. Quantity discounts are also frequently allowed. These vary from special prices on large purchases of a particular product to discounts on orders of a certain size for certain named products. Several firms, for example, offer special prices on large orders of tablets. Usually, newer and patent-protected products are excluded.

146. Finally, some firms offer a straight percentage discount on orders of a certain size. Cyanamid, for example, allows an additional 10 per cent off on orders from \$50.00 to \$75.00 and 15 per cent off on orders over

\$75.00. This does not apply to purchases of certain products, nor apparently does it apply if some other special discount or deal price is applicable to a particular purchase.

147. It was mentioned above that some small firms allow the retailer a 50 per cent discount on ethical drugs rather than the more usual 40 per cent. Such firms frequently follow the policy of allowing the same 50 per cent discount to all customers - wholesalers, retailers, hospitals (and less sales tax), doctors, clinics, institutions, etc. In contrast, most of the larger firms allow doctors only 25 per cent off list. They are rather selective in the institutions to which they will sell directly, but those to which they do sell are usually allowed 40 per cent.

148. The retail druggist thus pays at least a 10 per cent higher price than a hospital would pay for the same drug and frequently pays an even higher differential. In reselling to a customer, he must, of course, take a markup on this already higher price. Actually, a druggist almost never decides independently on a percentage markup which he then applies to determine selling price. Rather, he sells at the manufacturer's list or suggested resale price. If he has been allowed a discount of 40 per cent off list in buying the drug and resells at list, the actual markup on cost will be $66\frac{2}{3}$ per cent. If the discount he has been allowed is less than 40 per cent, actual markup will be correspondingly lower.

149. It is not proposed to discuss the propriety of the markups taken by retail druggists. However, it should be noted that because markup is related to a percentage discount, it varies directly with the price of the product. If a product has a list price of \$1.00, a druggist will normally pay 60 cents and take a markup of 40 cents. If a product has a list price of \$10.00, a druggist will pay \$6.00 and take a markup of \$4.00. Thus, the markup in terms of dollars and cents increases with the list price and becomes quite substantial in the case of a drug which is high priced at the manufacturer's level.

150. Resale price maintenance is illegal in Canada and there is no evidence that drug manufacturers attempt to force retailers to maintain prices. In the United States, almost all drugs are subject to the so-called Fair Trade Laws in those States in which such laws are in effect. However, even under Fair Trade Laws, the consumer may have a chance to buy more cheaply than under

the practice which exists in Canada. Under Fair Trade Laws, the Fair Trade price is normally set at about 90 per cent of the suggested resale price. Thus, a product which carries a list price of \$8.50 may be sold by a retail druggist subject to a Fair Trade Law at any price between \$8.50 and \$7.65*. In one instance, when the Director asked a company why one of its products appeared to be sold at a disproportionately high price in Canada as compared to the price in the United States, an official remarked that:

"It is customary for pharmacists in many areas of the United States to deduct 10% from the List Price on most pharmaceutical products which may be sold over the counter . . ."

(Letter, January 18, 1960, File 2041)

This would presumably apply to what are sometimes referred to as "over the counter" ethical drugs.

151. Despite the fact that there is no legal compulsion to do so, in Canada manufacturers' list or suggested resale prices seem to be adhered to almost without exception by retail druggists. There appear to be several reasons.

152. First, most manufacturers' and distributors' price lists (except those setting out net prices to hospitals) usually show list or suggested resale prices. The actual prices to the wholesaler, the retailer, the dispensing physician and other trade buyers are determined by applying the applicable discounts. Thus, all down the line from the manufacturer, the list price is used and comes to be regarded as "the price". To put it another way, suppose a certain sized package of a drug carries a list or suggested resale price of \$1.00. A retailer would normally buy at a discount of 40 per cent or at a cost of 60 cents. However, he does not look on the article as one which he purchased for 60 cents and proceed to mark it up on that basis. Rather, the article is looked upon as the \$1.00 size of the particular product, to be sold at \$1.00, regardless of whether it was purchased under a special deal or on other more favourable than usual terms or whether it was purchased on less favourable than usual terms.

*The setting of the Fair Trade minimum price at 90 per cent of the list price in the case of antibiotics is referred to in the FTC Report at p. 159. The example given is taken from Drug Topics Red Book 1960 and prices shown are for Achromycin, 250 mg. capsules in packages of 16. An examination of the Red Book indicates that, while there are some variations, the Fair Trade price is usually about 90 per cent of the list or suggested resale price.

153. Second, not only do manufacturers' price lists show suggested resale prices, but wide use is made throughout the trade of a composite price book which shows the suggested resale price for virtually every product sold in a drug store, from the most complicated drug to items such as pocket combs. Use of this book tends to reinforce the concept of a suggested resale price being "the price" for any particular item.

154. Third, there is a strong moral pressure exerted in the trade against price cutting, any price cutting is considered to be unethical conduct and although this applies particularly to the sale of prescription drugs, it appears to be true of the sale of all drug products. A few illustrations will make this clear. In a letter to a member of the Council of the Ontario College of Pharmacy on September 19, 1957, the Secretary of The Thunder Bay Pharmaceutical Association wrote:

"At an executive meeting held last night, it was unanimously decided to report one of our members, viz. Bourke's Drug Stores Ltd., to the Infringement Committee of the Ontario College of Pharmacy re unethical advertising through newspaper and radio medium. The inference in this advertising implies that these stores supply general front shop items as well as prescriptions below the prices of their competitors.

We feel that this is a serious blow to the prestige and ethical practices of the district #14 and furthermore this particular type of advertising is contrary to section #306 of the Criminal Code of Canada. Therefore we would like you, as our member, to voice our opinion on this matter at the next council meeting."

(Serial 200)

Apparently the alleged unethical conduct consisted of advertising low prices.

155. In November 1959, a pharmacist in the Eglinton-Keele area of Toronto displayed a banner in his window reading "Pre-Christmas Special, Pick up prescriptions 10% OFF." As a result of the letter set out below, he was visited by an official of the Ontario College of Pharmacy to whom he explained that he was having difficulties with deliveries during the Christmas rush and wanted to encourage customers to pick up prescriptions rather than ask for delivery. When the banner appeared, four pharmacists in the area wrote the following letter to the Ontario College of Pharmacy (the letter mentions an alleged case of substituting one drug for another, but it seems clear that the banner was the chief cause of complaint):

"The pharmacists, in the Eglinton - Keele area, have always conducted their pharmacies in the manner prescribed by the Code

of Ethics. In this section of the city, particularly, we have always maintained the highest regard for professional standards.

We look with disfavour at any fellow pharmacist who conducts his pharmacy in a manner which brings discredit to the members in neighbouring pharmacies. Such a pharmacy is located at 2506 Eglinton West, in the name of Yale Drugs.

We have found that this pharmacist has been substituting well known branded medication for others of his own choosing. We call your attention to the recent Pfizer letter to you in this regard.

We would like to call your attention to the enclosed photographs taken on November 10th, 1959, reading "Pre-Christmas Special, Pick up prescriptions 10% OFF."

We, the undersigned, feel very strongly about [sic] the ethics of this pharmacist and would like to have him remove the notorious streamer at once. We would like to have him follow the Code of Ethics as enunciated in the Ontario Pharmacy Act or cease to carry on in this disreputable conduct. We feel that this method of doing business is not desirable and ask that the infringement committee convene at once to handle this situation.

We would expect that an answer be forthcoming at the earliest convenience.

Thank you for your attention."

(Serial 236)

156. As already noted, in 1959 a pharmacist, Norman H. Englander, opened a pharmacy in Honest Ed's discount house in Toronto following court action to force the Registrar of the Ontario College of Pharmacy to register a change of address. Mr. Englander sells drugs and fills prescriptions at prices below those charged by most pharmacists. The court action prior to the opening of the pharmacy caused a good deal of comment, including an article by Pierre Berton in the Toronto Star on June 11, 1959. Mr. Berton said, in part:

"I have a suspicion, however, that many pharmacists are confusing ethics with profit. What really worries them is Mr. Englander's determination to sell you and me drugs at less than the 'suggested' price."

The files of the Ontario College of Pharmacy contain copies of several letters written to Mr. Berton objecting to the article. One of these, not by an official of the College, included the following:

"If the example of Norman Englander would be followed, soon the whole industry and the country would be thrown into a chaos and an anarchy. This is just what has happened to the pharmaceutical profession in New York and some other places. All the sensible and honest people in the trade there now regret this very much, since anarchy - whether it is political or commercial - furthers only a few. You comment on the words 'free enterprise' without being the least aware of the presently changing mood of our Government on the Combines Act, as a result of 'predatory practices of certain individuals' which in the long run serve the interest of a few and harm many. If Norman Englander would have

been a 'clever man', which unfortunately he never was, he surely could have found many excellent ways of improving the lot of mankind, besides engaging in unethical practices which are unanimously opposed by all the members of his profession."

(Serials 227-29)

There is no suggestion that Mr. Englander engaged in any unethical practices except as that term appears to be used in the trade to embrace price cutting.

157. It should be noted that the Ontario College of Pharmacy's opposition to Mr. Englander opening a drug store in Honest Ed's premises appears to have been based on a suspicion that, by entering into a lease which stipulated that rental would be based on a percentage of sales, Mr. Englander was in effect giving Honest Ed's a proprietary interest in the store which would be contrary to the Pharmacy Act (because, under the Act, the proprietor must be a registered pharmacist). However, it is clear that, among individual druggists, the opposition to Mr. Englander arose because of his pricing policies.

158. Much of the August 1960 issue of Drug Merchandising is devoted to the operation of discount houses in the retail drug trade (and in other lines, such as toilet preparations, which are normally stocked by retail druggists). While the material is too extensive to be set out here, the Commission will be invited to consider it as informed comment on conditions in the retail drug trade throughout Canada.

159. Under both Federal and Provincial law, certain drugs may only be sold on prescription, and practices adopted in pricing prescriptions affect the prices paid by the purchaser. Prescription drugs normally reach the patient either through a hospital pharmacy or by being purchased, after presentation of a prescription, at a drug store. A limited quantity of prescription drugs is dispensed directly by doctors, clinics, etc.

160. Prior to the inception of the Federal-Provincial hospital plans, hospitals charged patients in several ways for drugs administered in hospital. In some cases there was a direct charge for the drugs used with the markup over cost being set by the hospital. In other cases the patient was charged a flat per diem rate which included the cost of all or most drugs. Now, the hospital plans cover the supplying of drugs so that, regardless of how the plan is financed in a particular Province, the cost of drugs is paid for under the plan rather than by the individual. All Provinces except Quebec

now participate in the hospital plan and it has been indicated Quebec is likely to establish a hospital plan shortly. This means that the prices charged for drugs sold on prescription chiefly affect those who, while not confined to hospital, require prescription drugs and obtain these by having a doctor's prescription filled at a drug store.

161. Whether drugs are supplied under a hospital plan or must be purchased by the individual requiring them is important in several ways.

This is illustrated by a news report in the Halifax Chronicle-Herald of February 26, 1960, part of which was as follows:

"In Nova Scotia patients who have been discharged from mental hospitals frequently have to be recommitted for care, because they are unable to afford high cost of drugs, Andrew Crook said in Halifax Thursday.

. . . .

Mr. Crook, executive director, Nova Scotia Division of the Canadian Mental Health Association, was speaking at a three-day institute on aspects in nursing in the mental health program, sponsored by the Dalhousie School of Nursing under the direction of Miss E. A. Electa MacLennan.

Delegates from the four Atlantic provinces heard his comments on problems of rehabilitation experienced by ex-patients returning into the community.

Frequently it was solely the use of tranquilizing drugs which maintained the stable, mental balance of a person seeking to re-establish himself in society, he said.

Bills of \$50 a month were common. 'There are few people who can constantly find this amount, or often a larger sum, month after month. But it costs \$210 a month to keep a patient in hospital.'"

162. Some general inquiries were made into the practices followed in pricing prescriptions in Ontario and in British Columbia. In Ontario, these inquiries indicated that many local groups of druggists, i.e., those in a particular city or area, for some years had formulae for determining prices of prescriptions. Documents in the possession of the Director contain references to practices adopted in Hamilton, Ottawa, Windsor and other places. The Provincial governing body, the Council of the Ontario College of Pharmacy, does not seem to have actively concerned itself with the matter until the possibility of either a National or Provincial health plan began to be discussed. The Council then took an active interest in the matter and from about November 1955 on, there was a great deal of discussion, and committees on health insurance and on prescription pricing met frequently. Professor H. J. Fuller of the Faculty of Pharmacy, University

of Toronto, was engaged to make various studies of costs in connection with prescriptions. Sometime prior to August 1955, Professor Fuller had developed "A Method of Estimating Professional Dispensing Fees", because there is a reference on one copy to its being reprinted at that time. Another copy of the same document in the possession of the Director is marked as being reprinted February 15, 1958, which would be at least the third reprinting. The first issue of a document under the same title but prepared by a Special Committee on Prescription Pricing was published after approval at the November 1958 meeting of the Council. The latest edition in the possession of the Director is marked "Revised - January 1960". It would appear that Professor Fuller's suggested method was not too widely adopted, as local associations of druggists frequently preferred to stick to their respective local plans. The work of the Prescription Pricing Committee of the Council seems to have been largely devoted to reconciling the minor differences in local plans in order to arrive at a plan which would be generally acceptable. The Committee, after working on the matter for some years, finally adopted a plan which is now widely used by druggists throughout the Province. It is based on one originally developed by druggists in Essex County.

163. It may be noted in passing that the Essex County plan was adopted in conjunction with a prepaid prescription plan originated by druggists in Windsor and vicinity. The plan, known as the "Green Shield Prescription Plan" is similar in principle to prepaid medical plans and provides that on payment of a fixed monthly fee a subscriber is entitled to have any prescriptions filled by one of the druggists associated with the plan. The plan has attracted widespread attention among druggists throughout Canada. The following is a press report (Vancouver Sun, August 18, 1960) of discussion at the annual meeting of the Canadian Pharmaceutical Association:

"SASKATOON (CP) - Canada's first and only prepaid drug scheme, Prescription Services Incorporated of Windsor, Ont., is 10 per cent short of paying its own way.

The scheme, an Ontario-chartered non-profit organization which has been operating for the last 27 months, was the centre of interest as the Canadian Pharmaceutical Association held open-house to the public in the second-last day of its national convention.

Founder and president of Prescription Services, W. A. Wilkinson of Windsor, in the first public report on the prepaid drug scheme

revealed that, although all was not well with the project, approximately 90 per cent of those persons subscribing to the plan were 'paying their way.'

The other 10 per cent were 'costing money,' and were forcing the plan to charge a 10 per cent pro-rate against druggists in the plan.

He said that of 80 pharmacists in the Windsor-Essex County district of Ontario, only three had refused to join.

Under the plan, a subscriber pays \$1.90 a month for all prescribed medicines except vitamins, dietary supplements, insulin, diabetic products, and patent medicines upon presentation of his membership card and payment of 35 cents for each prescription.

A charge of 65 cents a month is made for each child.

Wilkinson reported that since the plan was started, more than 1,600 persons have joined and spent one or more months under its benefits."

164. As noted, the method of pricing prescriptions finally adopted in Ontario was a modification of the method originally used by the Essex County Pharmacists' Association. The latest revised edition (of January 1960) contains the amended provisions. Prescriptions are divided into two classes, those compounded by the pharmacist and those which involve dispensing drugs in the same form as that in which they are purchased.

165. For the first class, the rule is: Add the cost of drugs (at rate of smallest ordinary unit at wholesale) to cost of container and multiply result by two. Then add a service fee according to the scale set out. If the result does not equal the suggested minimum price set out, charge the minimum price. The scale of fees and the scale of minimum prices can be illustrated by showing those for a small and a large size of various dosage forms:

TABLE XXIII
ILLUSTRATIVE PRESCRIPTION FEES AND MINIMUM PRICES

<u>Dosage Form</u>	<u>Size</u>	<u>Fee</u> \$	<u>Minimum</u> <u>Price</u> \$
Liquids, compounded	$\frac{1}{2}$ oz.	1.00	1.50
	16 oz.	1.25	3.50
Drops, compounded, eye, ear, nose	$\frac{1}{4}$ oz.	1.50	2.00
	2 oz.	1.50	3.00
Internal	$\frac{1}{2}$ oz.	1.50	2.25
	2 oz.	1.50	3.00
Ointment, compounded	$\frac{1}{2}$ oz.	1.25	2.00
	16 oz.	4.25	5.50
Capsules and powders, hand- made	6	1.25	2.00
	100	5.25	6.00
Bulk powders, compounded	2 oz.	1.25	2.00
	16 oz.	3.25	4.00
Suppositories, hand-made	6	2.00	2.75
	24	5.50	6.25

166. The second part of the pricing guide consists of tables of prices to be charged for prescriptions for drugs which the druggist does not compound, but simply dispenses in the form in which he receives them. The pricing of full packages would be simple under any system, the chief function of the tables appears to be to give prices for any fraction of a package which may be called for. The prices in the tables are based on three factors (1) the list or suggested resale price for a full package; (2) whether a full or a part-package is called for, and (3) a professional fee. A distinction is made among packages having a list price up to \$9.00, packages having a list price between \$5.20 and \$15.00 and packages having a list price above \$15.00, and the formula varies in each case. For example, if a prescription calls for 25 tablets which the druggist purchases in 100 tablet packages at a list price of \$5.00 (the usual price to the druggist would be 60 per cent or \$3.00), the tables show a suggested price of \$2.55. This was apparently arrived at by taking 36 per cent (the percentage charged for one-quarter of a package in this price range) of the list price of \$5.00, which equals \$1.80, and adding 75 cents (the professional fee) for a total of \$2.55. If the list price of the package is between \$9.20 and \$15.00 or over \$15.00 different rules are applied. Thus, 25 tablets of a 100 tablet package with a list price of \$9.20 are shown as \$3.80. For a list price of \$15.20

the corresponding price is \$5.15. The suggested minimum price for any prescription is \$1.15.

167. Because different formulae are used where products have different list prices, there are certain anomalies in the tables. Examples were pointed out in a recent article reprinted in Drug Merchandising, May 1960. The author compares the suggested prices for 12 units (tablets, capsules, etc.) where the list price for a package of 100 is as shown:

"One of the most curious deficiencies of our latest OCP pricing guide is the remarkable role assigned to the magic list-price figure of \$15.00. The \$15.00 line on the chart forms a sort of water-shed from which prices roll down on either side.

To price prescriptions for one dozen units, this is what the chart would have us follow:

<u>List Price</u>	<u>12s</u>	<u>List Price</u>	<u>12s</u>
\$10.40	\$2.75	\$15.50	\$2.75
10.80	2.85	16.00	2.85
11.20	2.90	16.50	2.90
11.60	3.00	17.50	3.00
12.00	3.10	18.00	3.10
12.40	3.20	18.50	3.20
13.00	3.30	19.00	3.30
13.40	3.40	20.00	3.40
13.80	3.50	20.50	3.50
14.20	3.55	21.00	3.55
14.80	3.70	22.00	3.70
15.00	3.75	22.50	3.75

According to this topsy-turvy chart, a script for 12 of an item listing at \$10.40 should be priced exactly the same as one listing at \$15.50. But the one listing at \$15.00, it tells us, should be priced the same as one listing at \$22.50! To make it less confusing (if that were possible), one dozen units of a \$15.00 listed item would be priced at \$3.75. But at \$15.50 list, the prescription price for 12 drops one full dollar to \$2.75.

The reason for these wild discrepancies is that two methods are employed in setting the breakdown schedule - one for items listing up to \$15.00, and one for those over \$15.00. This involves an Alice in Wonderland logic we fail to follow. Surely the validity of something as important as a prescription pricing schedule lies in the universality of its method. A schedule which arbitrarily switches methods within itself is one which finds itself in an indefensible position. For to use a less severe breakdown for the 'over-\$15.00' class is an implied admission that the method used for the 'under-\$15.00' class is unduly severe.

To command respect, a pricing schedule must employ an equitable, consistent method of arriving at fees. Without that respect, the schedule commands little authority."

(p. 51)

168. General inquiries were also made into prescription pricing practices in British Columbia. These inquiries indicated that about 1945 a private organization was set up to furnish a pricing service to druggists. As presently operated, the service is as follows: On joining, a member buys

a book at a cost of \$35.00. This is in the form of a large, loose-leaf ledger listing virtually all items carried by a drug store. For non-prescription items, the book shows the name of each item, the sizes in which it is sold, and the suggested list price of each size. These list prices are manufacturers' list or suggested resale prices. For prescription items, prices are calculated according to a formula. If the cost to the druggist is \$3.60 or less (which would correspond to a manufacturer's list of \$6.00 or less), the rule is double the cost and add a 75 cent dispensing fee. If the list price is over \$6.00 and if the druggist receives a discount of 40 per cent off list, a dispensing fee of 75 cents is added to the list price. If the druggist does not receive 40 per cent off list, then for the purposes of the formula the list price is increased until it does reflect a discount of 40 per cent, then the 75 cent dispensing fee is added. In any of the foregoing cases, if a package has to be broken to supply the quantity called for by the prescription, a further 25 cents is added. On items which have a suggested list price of \$15.00 or over, the customer is charged the list price without any additional fees.

169. A formula is also provided for calculating the price of prescriptions compounded by the druggist. The formula provides for including a dispensing fee, double the cost of the ingredients and double the cost of the container. It also provides for a minimum price to be charged where the calculated price would be below the minimum price.

170. The service is kept up to date by weekly bulletins. The cost of the service (in addition to the cost of the basic book) is \$50.00 per year.

171. On February 29, 1959, the Registrar of the Pharmaceutical Association of the Province of British Columbia replied to an inquiry from a professor of the University of Manitoba asking for information about prescription pricing practices in British Columbia. The Registrar replied, in part:

"As you probably know, the B. C. Association does not have or recommend a price guide to our members. Some 85% of the stores in the province, however, subscribe to Druggists' Bulletin Service Ltd., an independent price book service. D.B.S. contains an individual listing of all items sold in retail pharmacies (including sundries) and is amended by weekly amendment sheets. The dispensing section of the book is presently compiled on the basis of a pricing formula as per the enclosed outline. I understand that consideration is presently being given to amending some aspects of this formula but am not familiar with the form these amendments will take."

(Serial 301)

The enclosure referred to in the letter was as follows:

"DRUGGISTS' BULLETIN SERVICE PRICING FORMULA"

1. Suggested minimum price on any prescription is \$1.25.
2. On prescriptions compounded in the dispensary: double cost of container and ingredients plus seventy-five (75) cents dispensing fee will apply. Prescriptions taking more time than five (5) minutes should be priced on the time factor at eight (8) cents per minute.
3. (a) Prepared specialties costing up to and including \$3.60 will be priced at double cost plus seventy-five (75) cents dispensing fee. Broken quantities the same, plus a twenty-five (25) cent premium.

(b) Where the cost is over \$3.60 the mark-up will be 40% (list) plus seventy-five (75) cents dispensing fee. On broken quantities, the same mark-up plus a twenty-five (25) cent premium.

(c) On prescriptions that cost over \$9.00 (\$15.00 list) no dispensing fee will be added.
4. Certain well known 'over the counter' items will be priced at list price plus dispensing fee of seventy-five (75) cents.
5. Narcotics: double cost plus seventy-five (75) cents dispensing fee, plus narcotic registration fee of fifteen (15) cents.
6. Injectables: list price."

(Serial 302)

172. The proposed amendments to the formula used by Druggists' Bulletin Service Ltd. are also referred to in a letter of February 9, 1960, from the Chairman of the Pharmaceutical Economics Committee of the Association to the Chairman of the Professional Fees Committee. The letter reads:

"At a recent meeting of the Pharmaceutical Economics Committee discussion ensued on the widespread discrepancy in prescription prices from pharmacy to pharmacy in British Columbia. The committee felt that while some element of differential of pharmacies was a logical and perhaps desirable result of the free enterprise system, the degree of differential was in many cases out of all proportion. The committee felt, however, that one of the principal causes was the system presently being used for computing prescription prices by the Druggists' Bulletin Service.

We were advised that your committee is also concerned with this question and that you have already made arrangements to discuss this matter with the principals of the above mentioned Service. The committee has instructed me to acquaint you with our concern in this matter and urge that your committee make all possible representations to the proper quarters to alleviate this situation."

(Serial 293)

173. The British Columbia Association has had committees working on professional fees and prescription prices since at least 1951. In 1958, a legal opinion was obtained which pointed out that any agreement on

prescription prices might constitute price fixing and would violate the anti-combines legislation, and this seems to have impressed on the committees and the Association the necessity of avoiding any such agreement. Apparently, efforts are now being directed towards having the formula used in compiling the Druggists' Bulletin Service amended. This formula was previously amended by increasing the dispensing fee from 50 cents to 75 cents. The publishers of the Service apparently hold no fixed views on prices, but try to put out a service which reflects the ideas of most of their clients. They have, on occasion, circularized subscribers to ascertain their views (Serials 374-75).

174. The Manager of Druggists Bulletin Service Ltd. advised a member of the Director's staff that the Service was also widely used in Alberta. Apparently this was the case until the annual convention of the Alberta Pharmaceutical Association in June 1960. Part of the report on the convention in Drug Merchandising, July 1960, reads as follows:

"EDMONTON - Adoption of a uniform pricing system for prescriptions and the issuance of a training manual for pharmacy internes featured the 49th annual convention of the Alberta Pharmaceutical Association held in Edmonton's Macdonald Hotel.

. . .

The standardized pricing program - designed to standardize the cost of identical prescriptions throughout the province - was brought before the convention by Jim Clarke of Calgary, chairman of a special committee set up last November to study the matter. It had been pressed for in particular by Edmonton druggists.

Under the new system, pharmacists will be supplied with a schedule which will give the cost to a customer for a prescription by calculating the cost to the druggist, plus his professional fee and mark-up.

Previously, prices were arrived at by consulting a bulletin service. This, according to Mr. Christopherson, involved a certain expense to the pharmacist, so subscription to the service was not province-wide.

Pointing out that pharmacists were not being forced to follow the new price schedule, Mr. Christopherson said he expected 90 per cent of them will. He said the public will have to pay more for some prescriptions under the scheme, but on the other hand, other prescriptions will be less." (pp. 28 and 43)

175. The Canadian Pharmaceutical Association has also interested itself in the question of pricing of prescriptions. Following the Association's annual meeting in August 1959, the Ontario delegates reported on their attendance, and their report includes the following:

"PHARMACEUTICAL ECONOMICS: (a) To facilitate compilation of a C.Ph.A. Prescription Pricing Guide, each province is requested to submit to the C.Ph.A. office, 12 copies of its provincial pricing guides and these in turn will be forwarded to each member of the committee for report next February; . . ."

(Minutes, semi-annual meeting, Ontario
College of Pharmacy, November 1959,
p. 1565)

That this was done is confirmed by the following letter from the Secretary-Manager of the Canadian Pharmaceutical Association to members of the Canadian Pharmaceutical Association Economics Committee on December 4, 1959:

"Last week, under date of November 30, 1959, my office forwarded to you copies of Prescription Pricing Guides used in various provinces. Copies of the so-called 'Shine Pricing Schedule', which is generally used as a guide in the province of New Brunswick, have been obtained from the Central Pharmaceutical Journal, Chicago. One copy is enclosed herewith.

Please include this in your review of pricing methods. Your comments and recommendations towards the establishment of a Suggest [sic] Canadian Prescription Pricing Method are urgently required by the chairman of the Pharmaceutical Economics Committee, Mr. W. R. Labow, 4504 Coolbrook Avenue, Montreal 28, Quebec."

(Serial 265)

176. Copies of the prescription pricing guides referred to included documents relating to practices in Manitoba, Quebec, New Brunswick and Nova Scotia. (The documents formed part of the correspondence from the Secretary-Manager of the Canadian Pharmaceutical Association as found in the files of the British Columbia Association.)

177. Manitoba. An undated document stamped "MANITOBA" is headed "DISPENSING FEE SCHEDULE (Suggested for Guidance)". The following extract will indicate its provisions:

- "1. Minimum price for any prescription 90c.
2. Pricing method to be used:
 - (a) Use list price of smallest regular size closest to prescription.
 - (b) For regular prescription add 75c.
 - (c) Prescriptions for Schedule F Drugs and Oral Narcotic Drugs add 90c.
 - (d) Prescriptions for Non Oral Drugs add \$1.15.
 - (e) Above pricing to be for prescriptions taking up to 15 minutes. Extra time at the rate of \$1.40 for 15 to 30 minutes, \$2.85 for 30 to 45 minutes and \$5.75 for 45 to 60 minutes. No additional fees.

- (f) Where cost only is available use following formula:
Cost times $\frac{5}{3}$ a list price allowing 40% discount.
Example: Cost is \$1.05 $1.05 \times \frac{5}{3} = \1.75 .

3. Original Sizes.

- (a) Regular prescriptions list price plus 35c.
(b) Prescription for Schedule F Drugs and Oral Narcotic Drug products add 50c.
(c) Prescriptions for non Oral Narcotic Drugs add 85c."

(Serial 272)

178. Quebec. A document (Serials 261-64) marked "4th edition, June 1959", is headed (this is a translation, original is in French) "Schedule of Prices, Prescriptions - Specialties, for the use of pharmacists and assistant pharmacists of the Province of Quebec, published by The Association of Retail Pharmacists of Montreal and of the Province of Quebec Inc." The document contains rules for pricing prepared dosage forms and dosage forms compounded by the druggist. The document does not state what dispensing fee is incorporated, but it seems clear that there is one. Thus, the table shows that where the list price of 100 tablets is between \$1.00 and \$1.24, the price charged for 75 tablets would be \$1.50. Presumably, the price for 100 tablets would be higher and therefore more than \$1.00 to \$1.24. Similarly, it is clear that a dispensing fee is included in the prices given for dosage forms prepared by the pharmacist.

179. New Brunswick. The information indicates that the "Shine" method - so named because it was developed by J. J. Shine in the United States - is generally used in New Brunswick. The basis is stated to be:

"THE CALCULATING RULES ARE:

Less than $\frac{1}{4}$ of the container - 150% Markup on Cost.
 $\frac{1}{4}$ but less than $\frac{1}{2}$ of the container - 125% Markup on Cost.
 $\frac{1}{2}$ but less than the whole - 100% Markup on Cost.
The full container or any original package - 75% Markup on Cost.

- (1) All prices to be computed on hundreds or pints, or the smallest available packaging over the amount dispensed.
- (2) After the percentage calculation is made, a 55c professional service fee is added.
- (3) If larger containers are used, such as gallons and thousands, the container should carry the cost per hundred or pint and the calculation determined from this figure.

COMPOUNDED MIXTURES

The rule for calculation is: Cost of ingredients and container, plus 100% markup on ingredients and container, plus time of the pharmacist at the rate of 10c per minute."

(Serial 269)

180. Nova Scotia. A document setting out prices and formulae for calculating prices of prescriptions is marked "Chart adopted by Halifax Retail Druggists Association, June 1959" (Serials 267-68). An explanatory letter contains the following paragraph:

"I am enclosing a printed schedule being presently used by The Retail Pharmacists in the Halifax area. In the main it is a copy of the new Schedule being used I believe in Ontario. Throughout the rest of the Province the majority of retail outlets are using Professor Fuller's older schedule reprinted February 15th., 1958."

(Serial 266)

181. Information about practices in Saskatchewan was obtained from the Registrar of the Saskatchewan Pharmaceutical Association. The situation in that Province is somewhat different because certain prescriptions are paid for by the Provincial Medical Services Division. The Registrar supplied copies of a Schedule which has been in use for some time and a newer Suggested Guide, and commented in part:

"The only prescription schedule or guide adopted by our Association was agreed to September 1st, 1947, when a contract was entered into with the Provincial Medical Services Division to supply drugs to all Government Wards. This was based on a cost plus plan with extra fees for compounded medicines, and was an ever failing source of confusion to all concerned due to variations in cost according to source of supply and quantity purchased.

During 1956 and 1957 we made a lengthy study and in 1958, April 1st, through a new agreement with our Government, a revised schedule was agreed to and adopted for use in rendering accounts to the Medical Services Division by our pharmacists. This proved to be an increase of approximately 10% and created an uniformity of pricing which was desired by Medical Services Division. In many instances this guide or schedule was used by pharmacists for all prescriptions.

. . .

Many of our pharmacists felt that their contract was not adequate for general use due to the large increase in inventory occasioned by the multiplicity of drugs required to give complete service which is available after hours as well as regular store hours, and due to the loss of graduates because of salary differences in other provinces.

After considering the above factors, a further survey has been conducted by gathering seven or eight thousand prescriptions at our office to help finalize a new suggested guide for general use. Following this study a new guide was prepared by our committee. This was built around the actual costs involved and this proposed guide is now on trial but does not set the price. Our professional

association does not pretend in any way to control prices of prescriptions.

. . ."

(Letter, June 23, 1960)

The new Suggested Guide provides for a professional fee of 25 cents to be added to the regular list price when the manufacturer's original package is resold. When the manufacturer's original package must be broken to fill the prescription, the proportionate price of the part used is calculated and 75 cents is added (10 cents for container, 15 cents for breaking package and 50 cents professional fee). When a prescription is compounded by the pharmacist himself, the suggested dispensing fee varies with the number of ingredients and the quantity prepared, as in the case of guides used in other Provinces.

182. It must, of course, be remembered that the pharmacist is under a heavy responsibility in dispensing drugs and that compounding or filling a prescription differs from an ordinary sale in which only commercial considerations are involved. The regulations which require that certain drugs be sold to consumers only through drug stores under the supervision of properly qualified pharmacists are part of the control exercised over the sale and distribution of drugs. The effectiveness of that control depends in a large measure on the integrity of pharmacists and the care which they exercise in performing their functions. Moreover, since a prescription must be kept on file, may involve checking with the doctor who wrote it, may entail entries in narcotic or poison registers and similar additional steps, it usually takes more time and effort than an ordinary sale. These and similar considerations are the reasons why pharmacists charge a fee, in addition to the price of the drugs, when filling a prescription.

183. The information obtained about prescription pricing practices and the general discussion of this subject reported in minutes of meetings of pharmacists' associations and in trade publications appears to warrant the following observations.

(1) It is the normal practice for dispensing pharmacists to include in the prices charged for prescriptions a fee covering their professional services. This fee is referred to as a prescription, dispensing or professional fee. The fee charged varies and is sometimes

not included where the list price of the drug sold is above a certain amount.

(2) Guides to or schedules of suggested prices to be charged for prescriptions are commonly used. Normally, these are relatively simple. The Druggists Bulletin Service in use in British Columbia (and formerly in Alberta) is exceptional and is much more detailed in form than those in use elsewhere.

(3) Although they differ in detail, the guides or schedules are similar in principle and two sets of prices, one applicable where a prepared dosage form is sold, the other applicable where the pharmacist actually compounds the prescription, are set out.

(4) Unquestionably, these guides are a convenience to the pharmacist, especially in pricing prescriptions which call for quantities which require breaking the manufacturer's standard-sized package and for prescriptions which must be compounded by the pharmacist.

(5) There is no clear evidence of formal agreement by pharmacists to adhere to these guides. On the other hand, they are, in fact, widely followed. Moreover, the fact that these guides are in some cases prepared by a committee of a professional association and published by the association probably tends to further their acceptance by the druggists to whom they are supplied.

(6) There is a strong and frequently expressed opinion among druggists that prescription prices should not be the subject of price competition. Such competition is regarded as demeaning to the status of pharmacists as professional persons and not mere merchants.

(7) In the result, it is clear that prices charged for prescriptions are substantially affected by the widespread use of guides or schedules of suggested prescription prices. These guides have the general effect of producing uniform prices for comparable prescriptions in any particular area.

CHAPTER X

EXPENDITURES OF SELECTED FIRMS ON ADVERTISING, RESEARCH AND QUALITY CONTROL

184. In May 1960, a number of selected firms were asked to submit details of their expenditures during the preceding year on advertising and promotion, on research and development of products and on grants to hospitals and universities, and on quality control. The expenditures reported are set out as a percentage of the value of the sales of each firm in the following table. The following points should be noted.

(a) The figure used for sales is the net sales of each firm. Some firms reported net sales, others reported gross sales and then showed sales tax, goods returned, etc., as expenses. In the latter instances, net sales were computed from the information supplied.

(b) Many firms stressed the difficulty of supplying precise figures on certain expenditures because such expenditures were not segregated in their accounts, or because of the necessity of apportioning fixed costs among various items, or similar reasons. Certain figures are therefore not exact.

(c) In a few cases it was necessary for the Director to apportion certain expenditures to conform to the breakdown used in the table. While this was done on the basis of the information supplied, it means certain figures are also approximations, although they are believed to be substantially correct.

(d) In the case of two firms, expenditures shown for research cover contributions to parent or related companies for research carried on outside Canada rather than the cost of research carried on in Canada.

(e) Several of the firms from which information was obtained asked that it be treated as confidential and for this reason the firms are not identified in the table. The information was obtained from the following:

Abbott
Ames
Ayerst
Bristol
British Drug Houses
Burroughs Wellcome
Canada Pharmacal
Ciba
Cyanamid
Dymond
Frost
Hoffmann-La Roche

Horner
Lilly
Merck
Parke-Davis
Pfizer
Pitman-Moore
Poulenc
Riker
Schering
G. D. Searle
Smith Kline & French
Squibb
Upjohn
Winthrop
Wyeth.

The firms do not appear in this order in the table.

TABLE XXIV

EXPENDITURES OF SELECTED FIRMS ON ADVERTISING
AND PROMOTION, RESEARCH AND QUALITY CONTROL
AS A PERCENTAGE OF NET SALES

FIRM	A	B	C	D	E	F	G	H	I
NET SALES	100%	100%	100%	100%	100%	100%	100%	100%	100%
ADVERTISING & PROMOTION									
Detail men & salesmen ..	4.61	13.74	32.79	12.01	23.79	11.81	11.22	23.91	11.10
Advertising in Journals, etc.	0.66	0.51	0.74	1.76	4.33	1.91	2.70	2.63	2.16
Co-operative advertising	nil	nil	nil	nil	nil	0.72	nil	nil	0.03
Direct mail	4.14	3.14	4.59	9.01	0.22	2.89	5.69	5.50	1.45
Samples	0.69	3.54	2.32	5.68	nil	2.32	3.55	3.75	2.29
Other	0.10	0.34	0.24	2.43	nil	1.61	0.76	0.92	1.50
Total	10.20	21.27	40.68	30.89	28.34	21.26	23.92	36.71	18.53
RESEARCH									
Research by firm	0.78	nil	0.56	nil	nil	3.80	nil	nil	7.39
Grants to Hospitals, Universities, etc.	0.08	0.72	nil	1.61	0.01	0.25	0.73	nil	0.61
Total	0.86	0.72	0.56	1.61	0.01	4.05	0.73	nil	8.00
QUALITY CONTROL	0.68	2.14	0.33	0.91	nil	1.42	0.67	nil	2.65

(Cont'd overleaf)

TABLE XXIV (Cont'd)

EXPENDITURES OF SELECTED FIRMS ON ADVERTISING
AND PROMOTION, RESEARCH AND QUALITY CONTROL
AS A PERCENTAGE OF NET SALES

FIRM	J	K	L	M	N	O	P	Q	R
NET SALES	100%	100%	100%	100%	100%	100%	100%	100%	100%
ADVERTISING & PROMOTION									
Detail men & salesmen ..	17.25	14.57	15.66	13.72	19.28	7.13	14.80	10.52	6.84
Advertising in Journals, etc.	2.24	0.65	1.14	0.09	1.60	1.26	0.65	1.59	2.20
Co-operative advertising	nil	nil	nil	nil	nil	nil	nil	nil	nil
Direct mail	1.40	3.15	3.97	0.44	7.07	13.61	4.02	2.04	2.59
Samples	1.46	7.50	4.75	3.72	3.64	1.55	3.48	4.50	0.77
Other	nil	0.75	nil	1.17	0.28	2.03	nil	0.42	1.36
Total	22.35	26.62	25.52	19.14	31.87	25.58	22.95	19.07	13.76
RESEARCH									
Research by firm	1.41	5.24	5.40	nil	nil	2.26	nil	0.42	1.79
Grants to Hospitals, Universities, etc.	0.15	0.24	0.87	nil	nil	0.45	0.45	0.08	nil
Total	1.56	5.48	6.27	nil	nil	2.71	0.45	0.50	1.79
QUALITY CONTROL	1.61	1.28	1.17	nil	nil	1.06	0.75	1.20	0.88

(Cont'd overleaf)

TABLE XXIV (Cont'd)

EXPENDITURES OF SELECTED FIRMS ON ADVERTISING
AND PROMOTION, RESEARCH AND QUALITY CONTROL
AS A PERCENTAGE OF NET SALES

FIRM	S	T	U	V	W	X	Y	Z	AA
NET SALES	100%	100%	100%	100%	100%	100%	100%	100%	100%
ADVERTISING & PROMOTION									
Detail men & salesmen ..	23.88	39.31	9.68	15.98	9.55	7.37	11.36	9.95	11.17
Advertising in Journals, etc.	1.57	8.91	3.36	1.74	2.78	1.11	1.66	0.49	2.18
Co-operative advertising	nil	nil	nil	nil	nil	0.09	nil	0.06	nil
Direct mail	2.36	nil	7.39	4.24	2.55	2.39	1.11	0.74	3.11
Samples	3.82	1.95	4.79	11.01	6.50	4.15	4.35	1.42	2.84
Other	0.18	1.38	0.24	1.33	1.02	0.86	0.20	0.15	1.60
Total	31.81	51.55	25.46	34.30	22.80	15.97	18.68	12.81	20.90
RESEARCH									
Research by firm	nil	nil	1.51	nil	0.02	nil	0.20	nil	2.03
Grants to Hospitals, Universities, etc.	nil	nil	0.79	nil	nil	0.44	0.48	0.01	0.79
Total	nil	nil	2.30	nil	0.02	0.44	0.68	0.01	2.82
QUALITY CONTROL	1.17	nil	nil	0.23	0.87	0.70	1.86	0.90	2.61

CHAPTER XI

ADVERTISING AND PROMOTION

185. As already noted, the advertising to the general public either of any drug which may only be sold on prescription or of any drug as a treatment for certain specified diseases or conditions is prohibited. Because of these prohibitions, most ethical drugs (in the wide meaning of the term as defined above) are not advertised to the general public, but only to doctors, pharmacists and others directly concerned with the prescribing or recommending of such drugs or with their sale.

186. The advertising and promotion of such drugs to those directly concerned is carried out by several means. Advertisements are placed in scientific, professional and technical journals and in druggists' trade journals and similar publications. Advertising is also sent out by direct mail. As part of the information requested from selected firms, each was asked to supply a copy of each piece of advertising material distributed by direct mail to doctors, pharmacists, etc., during the last six months of 1959. This material will be before the Commission and will illustrate the amount and nature of the material thus distributed. Wide use is also made of detail men. These are employees whose principal function is to call on doctors and explain the advantages of a firm's products, particularly its specialties and any new products which the firm brings out. Samples are distributed both by detail men and by direct mail and again are most widely used in connection with the introduction of new products, although this is by no means their only use.

187. Besides these direct forms of advertising and promotion many firms in the drug field, in common with those in other fields, use indirect forms of promotion designed to foster goodwill toward the particular firm. For example, a writer in Harper's Magazine, May 1960, p. 79, referring to the situation in the United States said:

" . . .

Little presents are often sent along with the literature and samples, such as lavishly illustrated cutouts, desk calendars, pen holders, pillows, and 'Queeg balls.' Roerig [presumably J. B. Roerig & Co., a division of Chas. Pfizer & Co. Inc.] provides woolen socks embroidered with the name of the product. Recently Wallace Laboratories sent physicians a record with an Oistrakh violin solo on one side and a product plug on the other.

. . ."

His comments would be equally applicable to Canada. Along slightly different lines, one Canadian firm financed tours of its U.S. parent plant by the graduating classes of certain medical schools, and another supplied each of the graduating doctors with a supply of calling cards. These are typical examples of the general promotional activities carried out.

188. In the requests for information sent to selected firms, the following question was asked:

"(j) Generally, how are the informational and promotional expenditures of the Company divided as between new products and Company specialties on the one hand, and more standard products that are also sold by other drug manufacturers on the other hand?"

The following are the replies received:

Abbott

"Generally the bulk of promotional expenditures are made on products which are competitive."

Ames

"The Company sells specialties only."

Ayerst

"On the assumption that this query applies only to the informational and promotional material referred to in the preceding paragraphs (g), (h), and (i), the expenditures involved would be divided approximately as follows:

New Products and Company specialties	80%
Other	20%
	<hr/>
	100%"

Bristol

"Since the marketing of new products requires the rapid dissemination of information about its uses, characteristics, limitations, precautions, etc. to the medical profession, promotional expenditures are generally high on new products in comparison to their sales volume. The remaining expenditures would be largely on company specialties, with relatively little expenditure on products generally well known to the medical profession."

British Drug Houses

"Greatest proportion expended on new products and Company specialties."

Burroughs Wellcome

"Informational and promotional expenditures are in the main related to new products and Company specialties, as the Company manufactures very few so called standard products."

Canada Pharmacal

"100% to new products and Company specialties with the exception of institutional advertising."

Ciba

"All promotional expenditures relate to new products and Company specialties."

Cyanamid

"Generally most of the informational and promotional expenditures of the Company are for new products and Company specialties."

Dymond

"No distinction."

Frosst

"Generally speaking informational and promotional expenditures are confined to new products and company specialties whether or not the latter are sold by other drug manufacturers and which in some cases could be classified as 'more standard products'."

Hoffmann-La Roche

"Our company manufactures and sells pharmaceutical specialties which come from our own research and are not directly comparable, as for composition, to items of other houses."

Horner

"Company sells specialty items only."

Lilly

"Practically all of our line in Canada is made up of Company specialties and practically all informational and promotional expenditures are directed to these products."

Merck

"Informational and promotional expenditures are practically all made on specialty products. We distribute very few standard type products."

Parke-Davis

"There is no general method of dividing informational and promotional expenditures as between various types of products."

Pfizer

"Pfizer Canada does not in promotional expenditure distinguish as between new products and Pfizer specialties on the one hand and standard products also sold by other drug manufacturers on the other. However, promotional activity generally emphasizes new products. For older established products considered as Pfizer Canada specialties which have gained acceptance, any information which sheds light on new applications, clinical trials or new dosage forms is brought to the attention of likely users. Standard products that are sold by other drug manufacturers receive only passing mention in printed promotion and listing in catalogues."

Pitman-Moore

"We consider that any preparation sold under a trade mark is a specialty. On this basis more than 70% of our products are specialties and we estimate that specialties account for more than 90% of total sales. Every one of these specialties encounters direct

competition by competing companies with closely competitive products. All of the informational and promotional expenditures (exclusive of selling and detailing expenditures) were directed to a small group of specialties. We do not know what you mean by 'new products' but the small group of specialties referred to above, while involving ingenious innovations, would probably not be considered 'new' by the average physician."

Poulenc

"Nous ne faisons aucune répartition de frais d'une part pour les spécialités et les nouveaux produits et d'autre part pour les produits réguliers qui sont également vendus par d'autres manufacturiers de médicaments. Nos ventes de produits de cette dernière catégorie sont d'ailleurs infimes."

Riker

"We had no new products in 1959. Generally, the only difference would be in the cost of the initial promotion. Index cards, samples, etc. i.e. we are getting ready to launch a new product now. Cards, sample material, etc. will run close to \$2,000.00. However, of this amount about all but \$500.00, the cost of the samples, we consider routine for any product. Other older products receive proportionately the same advertising and sample promotion."

Schering

"Promotional expenditures are concentrated on new products and company specialties, the more standard products receiving relatively minor support. For instance, the division of expenses in 1959 was as follows:

Company specialties and new products	\$258,760
Other products	135,750."

Searle

"A division between informational and promotional expenditures between new products and more standard products. Only new products are promoted through the medium of direct mail and older products are advertised periodically in the medical journals. The latter part of Item J. is not applicable as no other drug manufacturers sell our products."

Smith Kline & French

"The Company markets only its own specialties."

Squibb

"When a new product is developed, complete clinical, scientific and technical data and all other information are supplied to physicians. Special attention is given to explanations of any contraindications, potential toxic manifestations, etc. Also, when new indications, new potencies, and/or new forms of existing products are developed, physicians are likewise informed. Since this type of information is essential to keep physicians informed, it would be given whether or not other Manufacturers have similar products."

Upjohn

"100% on new products and specialties."

Winthrop

"Generally speaking, the informative booklets and pamphlets issued by Winthrop Laboratories of Canada Ltd. are intended to disseminate the correct manner of use of newer specialties or new uses for older products of our manufacture."

Wyeth

"With the exception of a very small group of galenical products, all the Company's products are marketed as Specialties. Each such specialty product competes with the same or similar products of other manufacturers. Generally it can be stated therefore that informational and promotional expense is applied in relation to products' current or potential sales volume. The estimated distribution being 75% to the more important specialties and 25% to the balance of the product line. Informational material is of course always available on every specialty product listed."

189. The expenditures of certain firms on advertising and promotion, stated as a percentage of net sales, have already been set out. The average for all the firms from which information on this point was obtained was almost precisely 25 per cent (actually 24.93 per cent). The significance of this percentage is emphasized if it is compared with the reported cost of goods sold. The percentage given above is for 27 firms. It was possible to calculate the cost of goods sold for 24 of these and the average for these showed cost of goods sold as 36.21 per cent of net sales. If two firms which, because of the nature of their operations, have relatively high costs of goods sold, are taken out, the average for the remaining 22 firms is 33.38 per cent. Thus, the cost of advertising and promotion is one of the major expenses of doing business and is, of course, reflected in the prices charged for the products sold. There was a wide variation in the expenditures reported by particular firms, but the figures show, and this is a matter of common knowledge, that the large ethical drug firms spend proportionately more than do small firms. These large firms employ numerous detail men and are able to launch massive campaigns to introduce new products. This can be illustrated by statements of officials of certain of these firms as reported in the FTC Report. These statements were based on affidavits filed in support of patent applications and were summarized in the Report* as follows:

". . .

Vice President W. G. Malcolm, of American Cyanamid Co., stated on October 4, 1955, that over \$20 million had been spent by his company as of that date in advertising Aureomycin. Vice President Thomas J. Winn, of Chas. Pfizer and Co., stated on August 5, 1952, that between January 27, 1950, and August 1952, Pfizer

*FTC Economic Report on Antibiotics Manufacture, p. 25, referring to affidavits of W. G. Malcolm, dated October 4, 1955, and Thomas J. Winn, dated August 5, 1952.

spent \$7½ million in the advertising and promotion of Terramycin.

. . ."

The large expenditures on advertising and promotion by the big ethical drug firms is admittedly one of the reasons why the products of such firms are frequently higher priced than those of smaller firms, in fact it is sometimes advanced as a justification for such prices (to the extent that prices reflect such expenditures).

190. Any such statement is based on the argument that the advertising and promotion carried out by the drug firms serve a useful and necessary purpose. Thus, in the return of information submitted by Hoffmann-La Roche, an official of that firm spoke of the work of detail men as follows:

" . . . There is definitely a big distinction to be made between a Detail Man and a Salesman. As far as Hoffmann-La Roche is concerned, we do not employ any Salesmen, but Detail Men only and are referred in our records as 'Medical Representatives.'

While Salesmen are mostly engaged in visiting commercial outlets, taking orders, making collections for delivered merchandise, etc., Medical Representatives of our company function as a semi-professional liaison between Canadian physicians, Universities, Governmental Health Institutions, Hospitals, and our firm. It is up to them to announce to the Medical Profession any new products introduced on the Canadian market and point out various specifications and qualities and important points concerning the drug, such as: Indications, Dosage and Administration, Properties of the drug and its Advantages, Contra-Indications and Toxicity Data.

Furthermore, Medical Representatives also bring to our attention various requests and information required by the Medical Profession or various Institutions which are then passed on to our Medical Department for reply."

Similarly, it is claimed that the printed matter sent to doctors gives them valuable information about drugs and enables them to properly evaluate various drugs and decide which should be used in particular circumstances. It is argued that, with the rapid developments in the drug field, a programme of disseminating information about new drugs and new findings about old drugs is essential to keep doctors informed.

191. The economic reasons for lavish promotion were reportedly referred to by an official of Horner in an interview in Vancouver. A press report in the Vancouver Sun of March 24, 1960, said:

"A drug company executive said here today there is no way to avoid the high cost of promoting new drugs.

Leonard Mitchell, vice-president in charge of research for the Montreal-based firm of Frank Horner Limited, said the intense

competition between drug manufacturers forces each company to send lavishly-decorated brochures to doctors followed by detail men to explain new drugs.

He said a company wouldn't stay in business if it didn't compete.

. . .

Mitchell, a UBC graduate, explained trade names play an important part in attracting a doctor's attention to a new drug.

He said if drugs had to be prescribed by generic name a doctor wouldn't remember half the drugs he should, because the names are often long and complicated.

'It's like a fad, or fashion,' he said, 'if a name catches on with doctors, the drug sells.'

192. On the other hand, there is a strong body of opinion which is highly critical of the advertising and promotional practices of the drug industry. Some of the main criticisms are that detail men are primarily interested in promoting the brand-named products of their respective employers and not in providing unbiased factual information, and that there are so many of them calling on doctors that they are a nuisance; that while some of the material sent to doctors is carefully prepared, much of it is essentially promotional in nature, is of no real value to the doctor in assessing the value of the drugs dealt with and, indeed, may be misleading because of emphasis on the beneficial properties of products and omission of or inadequate reference to dangerous properties; that it is impossible for the average doctor, without prolonged study, to separate the reliable from the unreliable; and that the great volume of the material distributed means that most of it is not read and studied, but simply discarded and is thus a sheer waste. There are other more basic objections such as that high-pressure promotion enables a multiplicity of substantially similar products which have no medical justification to be marketed and sold, and that the widespread use of complicated and potentially dangerous drugs for trivial illnesses is being encouraged.

193. An evaluation of advertising and promotion of drugs to the medical profession necessarily involves medical opinion and cannot be fully dealt with here. An article, "Doctors, Drugs and Drug Promotion" which appeared in The Canadian Medical Association Journal, April 1, 1959, volume 80, is set out in Appendix II. Another expression of medical opinion is

contained in the Report of the Committee on Pharmacy of The Canadian Medical Association to the annual meeting of the Association in June 1960. The following is an excerpt:

"142. The general situation with regard to drugs should be a matter of concern to this Association. New drugs are being introduced at a rate of more than one hundred per annum, and new combinations of drugs are being marketed in a way which creates confusion. Some of the new compounds represent real advances in therapeutics, while others have very little advantage over the older agents which they supplant so rapidly. When new agents are introduced at this rate there is no opportunity for sober evaluation of their merits or publication of the results of such studies before they are widely advertised to the profession. Nonetheless, the sale of most of these drugs is directly due to the fact that they are prescribed by doctors. Your Committee feels that there are two aspects to this problem. The first requires that the individual physician consider carefully the evidence upon which the claims for new drugs are based, and the actual advantage (or disadvantage) likely to be enjoyed by the patient for whom he contemplates prescribing them. The second has to do with the provision of greater facilities for clinical trials of new drugs and their publication by institutions capable of doing the work properly, possibly with the support of a pooled fund to which the pharmaceutical manufacturers would be willing to contribute.

143. The cost of drugs has been a matter of much discussion in recent months. There is no doubt that the pharmaceutical houses have made many contributions in past years to our ability to alleviate illnesses which in the aggregate represent an almost incalculable economic and humanistic gain to our community. There is some evidence to suggest that the return which they are receiving on their original investment is excessive. Your Committee is not in possession of sufficient factual evidence to pass judgment on this question, but there is no doubt that it is a matter which should concern this Association greatly. Many of the advertising practices of the drug houses appear wasteful and unprofessional. This applies particularly to direct mail advertising to the doctors. This has reached the point where it is nothing more than a nuisance to its recipients and your Committee would recommend that representations be made to the Pharmaceutical Manufacturers Association that it should be discontinued, and the saving passed on to our patients."

(The Canadian Medical Association
Journal, September 3, 1960, volume
83, p. 505)

194. There is evidence that some of the drug manufacturers themselves feel that promotional methods have gotten out of hand and that the present large expenditures are not justified. The following item appeared in Newsweek on May 16, 1960:

". . .

While the drug manufacturers are naturally reluctant to discuss strategy, they have already indicated clearly exactly where some of these steps will lead. The targets:

". . .

Promotion: Connor [John T. Connor, President of Merck & Co.] has admitted, and most other drug manufacturers agree privately, that promotion expenses - the huge volume of direct mail advertising to

doctors, visits by detail (promotion) men, and extensive advertising in medical journals - have gotten out of hand and must be checked.

. . ."

(p. 91)

CHAPTER XII

MEDICAL RESEARCH IN CANADA

195. In the course of the inquiry, an attempt was made to determine the extent and nature of medical research carried out in Canada and particularly to determine the extent and nature of research done by commercial drug firms.

196. Medical research in Canada (and in most countries) is done by four types of organizations: governments, universities, foundations and commercial firms. Research by Government foundations and universities will be considered first.

197. Before 1921, although research on medical problems was being conducted within the faculties of the medical schools in Canada, it was conducted on a limited scale. In 1921, the "explosive force"* of Sir Frederick Banting's discovery of insulin "started a chain reaction of enthusiasm in medical research which has expanded with increasing intensity to its present status".^{xxx} Medical research continued to be conducted mainly in the universities. The Rockefeller Foundation and other American agencies contributed to the medical schools in the form of research fellowships and grants^{xxxx} and, in the early nineteen thirties, the National Research Council and the Department of Agriculture gave some support to research in special fields related to human illness.^{xxxxx}

198. At the present time, the following organizations provide funds for medical research:

(1) The Federal Government

(a) National Research Council, Medical Division. This

Division was originally established in 1938 as the Associate

*Dr. G. H. Ettinger, "Medical Research", prepared for the Massey Commission and quoted by Dr. Basil D. B. Layton in "Financing Medical Research in Canada".

^{xxx}Dr. Basil D. B. Layton, "Financing Medical Research in Canada", The Canadian Medical Association Journal (Volume 76, pp. 534-41, 1957; Reprint p. 1).

^{xxxx}Dr. Basil D. B. Layton, op. cit., p. 1.

^{xxxxx}Special Committee Appointed to Review Extramural Support of Medical Research by the Government of Canada, Report to The Honourable Gordon Churchill, Chairman, The Committee of The Privy Council on Scientific and Industrial Research, known as The Farquharson Report, November 12, 1959, p. 3.

Committee on Medical Research and assumed its present form in 1946. Its principal terms of reference are "to initiate, stimulate, and coordinate medical research in Canada".^x

(b) Department of Veterans Affairs. This Department established in 1950 a research programme in its hospitals and clinics to study problems of aging, atherosclerosis, etc.,^{xx} and to evaluate ACTH and cortisone.^{xxxx}

(c) Defence Research Board, established in 1946, has a Medical Section which "focused its research interests upon problems having specific relation to health and its maintenance in the Armed Services".^{xxxxx}

(d) Department of National Health and Welfare in 1948 established the Health Grants programme which provides funds for research into several specific diseases and a Public Health Research Grant to provide funds for research not related to any one of the specified diseases.^{xxxxx}

- (2) Provincial Governments. Several organizations interested in medical research have been established such as, for example, the Ontario Cancer Treatment and Research Foundation and the British Columbia Medical Research Institute.^{xxxxx}
- (3) Voluntary Health Agencies. Since the end of World War II, numerous organizations have come into existence whose principal aim frequently is to support and encourage research devoted to some particular disease. The National Cancer Institute of Canada, The Canadian Cancer Society (this Society antedates the Cancer Institute), The Canadian Arthritis and Rheumatism Society, the National Heart Foundation, the Muscular Dystrophy Association, The Canadian Mental Health Association, and the Multiple Sclerosis Society of Canada are associations of this type.^{xxxxxx} The Ontario

^xThe Farquharson Report, p. 3.

^{xx}Layton, op. cit., p. 4.

^{xxx}The Farquharson Report, p. 18.

^{xxxx}Layton, op. cit., p. 2.

^{xxxxxx}Canadian Almanac & Directory, 1960. Layton, op. cit., p. 2.

Heart Foundation is fundamentally a voluntary organization but receives both Federal and Provincial financial support.

- (4) Foundations. Several foundations exist in Canada which have as their aim or among their aims the support of medical research. These are The Atkinson Charitable Foundation, the Banting Research Foundation, The Canadian Foundation for Poliomyelitis and Rehabilitation, Gardiner Medical Research Foundation, The R. Samuel McLaughlin Foundation, The Rockefeller Foundation, the Bickell Foundation, the Alcoholism Research Foundation and The Canadian Life Insurance Officers Association.*
- (5) Commercial Firms. Commercial firms in Canada support research both within and outside their own laboratories. This is discussed below.
- (6) Universities and Hospitals. The medical schools of universities and their affiliated hospitals, and other related faculties of universities are vitally concerned in medical research.

"The quality of medical care in any country depends upon the stimulus provided by its medical schools, for in them are concentrated progressive, scholarly and stimulating leaders in the various fields of medicine."**

- (7) Foreign Sources. The United States Government and various agencies have contributed to the cost of research done in Canada.

199. Without going into extensive detail, it is possible to generalize and say that the funds provided by the organizations mentioned above are distributed through various systems of grants-in-aid to individuals who have submitted research projects to the organizations for approval and to universities engaged in a research programme or to organizations engaged in some particular study such as the National Cancer Institute or the Alcoholism Research Foundation.

200. The Federal Government agencies listed do intramural research as well as providing grants-in-aid but the greatest portion is for grants-in-aid.***

*Canadian Almanac & Directory, 1960; Layton, op. cit., p. 2.

**The Farquharson Report, p. 2.

***Layton, op. cit., Table II, p. 3.

The National Research Council relies on grants-in-aid and concentrates on providing funds for basic medical research.^x The Department of Veterans Affairs gives grants-in-aid of research done in its own hospitals.^{xx} The Defence Research Board gives grants on an outright basis and has established and supports four special research units at the University of Manitoba, the University of Toronto, McGill University and in Ottawa.^{xxx} The Department of National Health and Welfare gives awards on the recommendation of a Provincial Minister of Health for study in various specified fields or under the Public Health Research Grant. This Department together with certain Provinces also gives funds to the National Cancer Institute to be distributed and used by that Institute.^{xxxx} The Department of National Health and Welfare is the Government agency which has contributed most to medical research projects.^{xxxxx} The creation of the new Medical Research Council may change the situation in the future.

201. The actual research is done by scientists and medical doctors in universities, working for foundations, or in teaching hospitals (as well as what is done in Government laboratories). The research may be of an applied or fundamental character and may involve clinical testing of substances.

202. The Connaught Medical Research Laboratories, University of Toronto, and the Institute of Microbiology in Montreal, produce vaccines as well as engaging in research. Considerable of the sums used to support the research work of these organizations comes from the sale of vaccines and, in the case of the Institute of Microbiology, some income is derived from work undertaken for commercial firms. Connaught receives gifts and grants from various organizations including the National Research Council and the Department of National Health and Welfare. The capital expenditures of the Institute of Microbiology are paid by the Government of Quebec and, aside from funds received from sales of vaccines and contracts from commercial firms, the

^xThe Farquharson Report, p. 12.

^{xx}The Farquharson Report, p. 18.

^{xxx}The Farquharson Report, p. 17.

^{xxxx}The Farquharson Report, pp. 15 and 16.

^{xxxxx}Layton, op. cit., Table I, p. 2, The Canada Year Book, 1959, p. 384.

Institute received grants from the Federal Government. Neither organization receives subsidies in any form from commercial firms.

203. Information concerning expenditures on research is not complete but the information which is available in compact form is reproduced below:

TABLE XXV
FUNDS AVAILABLE FOR MEDICAL RESEARCH IN CANADA,
ALL SOURCES, 1949-50, 1952-53 AND 1955-56

<u>Agency</u>	<u>1949-50</u> \$	<u>1952-53</u> \$	<u>1955-56</u> \$
Governments			
Federal (grants and fellowships) φφ	1,210,000	2,900,000	3,285,000
Federal (intramural)	110,000	1,060,000	1,170,000
Provincial (grants) φφ	155,000	190,000	345,000
Universities (local funds)	600,000	1,050,000	1,350,000
Voluntary bodies (grants)	225,000	700,000	845,000
Commercial (intramural, grants and fellowships)	750,000	950,000	1,600,000
Foreign (grants from U.S.A.)	210,000	420,000	595,000
Total	3,260,000	7,270,000	9,190,000

Source: Layton, op. cit., p. 3.

~~φφ~~Dr. Layton pointed out in the text of his article that the expenditures shown for 1949-50 may be incomplete due to the paucity of data for those years.

~~φφ~~Includes grants to National Cancer Institute.

204. Table XXVI below shows Federal Government support of research in establishments other than Government establishments. It demonstrates that extramural research support as a percentage of gross national product was 0.0123 in 1958-59 and was estimated to be 0.0145 in 1959-60. The Report contrasts these expenditures to those made by the National Institutes of Health in the United States of 0.0245 and 0.0349 per cent in 1958 and 1959 (estimated)^x, to those made by The Medical Research Council of the United Kingdom of 0.0128 and 0.0143 per cent in 1957 and 1958 (estimated)^{xxx}, and to those made by the Medical Research Council of Sweden of 0.0062 and 0.0078 per cent in 1957 and 1958 (estimated)^{xxx}.

^xThe Farquharson Report, Table 2A.

^{xx}The Farquharson Report, Table 2B. These expenditures represent approximately 50 per cent of the Government's total contribution to extramural medical research.

^{xxx}The Farquharson Report, Table 2C. Only about 15 per cent of the Swedish Government's total contribution to medical research is channelled through the Medical Research Council.

TABLE XXVI

FEDERAL SUPPORT FOR EXTRAMURAL MEDICAL RESEARCH, 1946-1960

Year	Extramural Medical Research Expenditure by Government of Canada					Gross National Product* (\$ billions)	Extramural Research Support as Percentage of G.N.P.
	National Research Council	Dept. of National Health and Welfare	Defence Research Board	Dept. of Veterans Affairs	TOTAL		
		(\$ Thousands)					
1946-47	158				158		
1947-48	271	150	40		271	15.12	0.0036
1948-49	357	326	113		547	16.34	0.0037
1949-50	498	720	179		937	18.01	0.0080
1950-51	539	959	542	1	1,439	21.17	0.0098
1951-52	578	1,248	357	0	2,079	24.00	0.0093
1952-53	617	1,639	380	2	2,663	25.02	0.0106
1953-54	642	1,600	365	1	2,618	24.87	0.0105
1954-55	652	1,554	404	2	2,653	27.07	0.0098
1955-56	693	1,740	419	1	3,009	30.18	0.0100
1956-57	849	1,937	373	18	3,222	31.4	0.0103
1957-58	894	2,000	409	17	3,949	32.2	0.0123
1958-59	1,523	(2,568)	(412)	(9)	(4,959)	(34.0)	(0.0145)
1959-60 (est.)	(1,970)						

* National Accounts - Income and Expenditure, 1926-1956, Dominion Bureau of Statistics, Ottawa, 1958, p. 33; and Canadian Statistical Review, August 1959, p. 6.

Source: The Farquharson Report, Table I following p. 34.

205. The Farquharson Report gives an impressive list of the achievements of medical research in Canada.

". . .

The dramatic discovery of insulin in 1921 focussed attention on Canadian medical research, stimulated the ambitions of young people to enter the field, and led the public to expect our scientists to make major contributions to medical science. This expectation has been justified. The full list of these can not be given now, but it would include: the isolation of hormones from the parathyroid gland, the pituitary body and the placenta; the introduction and use of anti-coagulants; the use of refrigeration in major surgery; the identification of the sex chromosome; the preparation of an artificial medium for the cultivation of mammalian cells; the discovery of the function of certain areas in the cerebral cortex; methods of surgical treatment of epilepsy; the discovery of the nature of certain diseases of the liver; knowledge of the variations in metabolism in health and disease; and a host of fundamental discoveries which fit into the general pattern of scientific knowledge. . . ."

(Farquharson Report, p. 1)

206. With the extension of knowledge of diseases and their treatment has come an ever-increasing difficulty in the problems yet to be solved and an ever-increasing need for more funds for research workers and equipment, and more space to house these workers and equipment. For the commercial firms the situation is summed up in an article in Fortune Magazine.*

". . . The essential problem remains: heavy spending on research is increasingly necessary to ensure survival, but the payoff from spending is diminishing to the point where some firms are likely to find themselves in trouble.

. . ."

207. The Farquharson Committee suggests that the financial support for medical research in Canada is inadequate and that further funds should be provided by the Federal Government.** It recommends, among other things, the establishment of a Medical Research Council to advise on policy and matters relating to medical research and to administer funds to support and encourage medical research in Canada, and recommends that the budget of this Council for 1960-61 be \$4 million and that substantial annual increments be provided. The Committee also recommends that funds be made available for construction of research buildings and facilities in medical schools and affiliated institutions, and estimates that \$25 million is needed for this purpose by medical schools and \$12 million by affiliated teaching

*Charles E. Silberman, "Drugs: The Pace is Getting Furious", Fortune Magazine, May 1960, p. 281.

**The Farquharson Report, p. 32.

hospitals.*

208. The Minister of Trade and Commerce announced on Wednesday, August 10, 1960, that the Government had approved the establishment of a Medical Research Council. In making the announcement, he stated that, for the moment, it would be part of the National Research Council but that later it would become a separate entity.**

209. The questionnaire sent to selected firms asked questions concerning expenditures on research both by the firms questioned and through grants made by these firms to hospitals, students, doctors, etc. Of the twenty-seven firms questioned, six firms reported that they did not carry out research of any significance in Canada. The following extracts are from their returns:

(1) Ames

" . . . the Company did not directly expend any amounts for research during 1959.

. . . the Company did not directly make any grants during 1959 to universities, hospitals or any other institutions or to individuals for the purpose of research, except that some drugs were furnished to such parties . . ."

(Return, May 24, 1960)

(2) Bristol

" . . . Because Bristol Laboratories of Canada, Ltd. is a subsidiary of Bristol-Myers Company, the Canadian corporation depends on its U. S. affiliate for research and development work. During 1959 Bristol Laboratories Inc., U. S. A., spent 16.1% of its sales on research, an amount equal to 15.1% of sales in the U.S.A. and Canada. The products and processes developed from this research are of direct benefit to Bristol Laboratories of Canada, Ltd.

During 1959 \$11,538 was paid to research consultants in Canada located at the University of Ottawa. These funds were expended by the Research Division of Bristol Laboratories Inc., U.S.A., and were not charged to the Canadian subsidiary. These expenditures covered a consulting agreement and University Grant for Biochemistry Research and a consulting arrangement and University Grant for Organic Chemical Research.

It is the opinion of the management of Bristol Laboratories of Canada, Ltd. that the profits of the company in Canada are overstated for the reason that no research is charged against the operation. It would be necessary to make an intercompany charge for such services. It has been our experience that the Canadian Department of National Revenue has not seen fit to allow charges levied on our Canadian subsidiary for administration or other services. It is therefore advantageous from an overall tax standpoint to refrain from making such charges."

(Return, June 24, 1960)

*The Farquharson Report, pp. 33-34.

**Ottawa Journal, August 11, 1960.

(3) Cyanamid

"No research programme is carried on by the Company in Canada. Occasionally a minor research project, such as some work on Temposil, is carried on in Canada. The cost of this work in 1959 amounted to some \$1,200.

5. All grants to universities, hospitals and other institutions, or to individuals, for the purpose of financing research in Canada during 1959 were made by American Cyanamid Company, 30 Rockefeller Plaza, New York 20."

(Return, June 10, 1960)

(4) Dymond

This company does no research.

(Return, May 10, 1960)

(5) Lilly

"There is no research programme conducted in Canada except that we have many doctors co-operating in the assessment of new drugs through a clinical trial programme.

. . . the following is quoted from the remarks of the President of our parent company at the annual meeting in March, 1960 -- 'Lilly spent more than \$18,000,000. on research and development last year--'

. . . all such grants [i.e., grants to universities, etc.] are made through the parent organization directly from U. S. A."

(Return, May 24, 1960)

(6) Searle

". . . there is no charge to the Canadian company for research by the Searle Laboratories in the United States. The proportionate share is a fairly high percentage of the sales dollar and at present volume, it is felt we would not be in a position to sustain such costs.

. . .

. . . there are no grants made at present by the Canadian company, although it is possible some awards are made by the parent company which are not charged to this operation."

(Return, May 26, 1960)

210. Table XXVII gives reported expenditures by selected firms on research. The firms were asked to supply information covering the year 1959 or the last financial year if the firm's financial year did not coincide with the calendar year. The totals shown include grants to hospitals, etc., as well as, in the case of two firms, direct payments to parent or related companies as contributions to the cost of research carried on outside Canada. As appears from Table XXIV above, several firms contributed to research only through grants to hospitals, etc. Generally, those firms which spent the most on research in an absolute sense also spent the most relative to sales. However, there were a few exceptions and,

[Note: Table XXVII, showing expenditures by individual companies on research, and Table XXXII, showing expenditures by individual companies on quality control, have been omitted from the copies of the Statement being distributed because they would provide a key to the identity of the companies listed by letters in Table XXIV above. The tables are included in the copies of the Statement supplied to the Commission.]

in one instance in particular, a firm having somewhat smaller sales than the larger firms reported as high a relative expenditure on research. On the basis of the information supplied by the selected firms, there appears to be no correlation between the rates of profit of particular firms and their expenditures on research.

211. The total sales of the twenty-two firms listed in Table XXVII were \$94.6 million so that the average expenditure on research by these firms would be 2.12 per cent of sales. Since several of the larger firms do not carry out research in Canada and since many small firms do not carry on any research at all, the total amount expended on research in Canada would undoubtedly be a smaller percentage of total Canadian sales of drugs.

212. Each firm was asked to outline briefly the type and scope of any research programme carried on in Canada. The following are particulars supplied by some firms:

(1) Ayerst

"The Company is involved in basic chemical, pharmacologic, and clinical research in several fields. Most of our projects result from our own research discoveries and developments, but we also collaborate with other research groups outside Canada. Our present activities are in the following fields of medical research:

Cardiovascular Studies:

New or improved peripheral and coronary vasodilators and
bronchodilators
Cholesterol-lowering compounds
Veratrum alkaloids (for hypertension).

Central Nervous System:

New mental stimulants
Tranquilizers

Peripheral Nervous System:

New Gastric secretion inhibitors
New long-acting antitussive drugs
New Potent antispasmodics

Endocrinology:

Basic research on natural estrogens
New synthetic sterols, such as oral progestational compounds,
anabolic and anti-inflammatory drugs, etc.

Cancer Research:

Investigation of experimental transplantable endocrine tumors and
search for indications of activity in many of the endocrine
type compounds being produced by us.

Special Microbiological and Fermentation Studies:

Chemical synthesis of molecules and their microbiological
transformation.

The research staff working on these projects involves approximately one hundred employees. Twenty-five of these have doctorate degrees in Medicine, Physical and Analytical Chemistry, Organic Chemistry, Biochemistry and Microbiology."

(Return, May 18, 1960)

(2) Frosst

"The research program of the Company may be divided into four sections. They are:

1. Chemical

- (a) Investigations directed to the discovery of new therapeutic agents and to effecting improvement in existing preparations.
- (b) Development of analytical methods for such new or modified compounds.

2. Pharmacological

The investigations carried out in the pharmacological laboratories are concerned with the study of biological effects and toxicity of new compounds prepared in our own laboratories, or those offered to us by others in order to obtain clues as to their therapeutic potentiality.

- 3. Support for and collaboration with clinical investigators of new products in hospitals. Our medical staff may or may not be directly associated with such investigations.

4. Pharmaceutical

Investigations concerned with the formulation of new and existing therapeutic agents in order to provide acceptable or improved pharmaceutical forms of these products."

(Return, May 24, 1960)

(3) Horner

"The Company has been engaged in scientific research and development in the pharmaceutical field since 1943. Present activities cover organic chemistry, biochemistry, pharmacology, bacteriology and pharmaceutical development (that is, problems relating to the preparation of new dosage forms, stability studies, etc.) and clinical trials of new drugs.

Some of the major problems investigated recently or under investigation are:

- 1) the preparation and possible uses of pituitary growth hormone
- 2) improvement of sulfonamide therapy by inhibiting the conversion of these drugs in the body to the inactive acetylated form
- 3) improvement of isoniazid therapy (in tuberculosis) by inhibiting the conversion of this drug in the body to the inactive acetylated form
- 4) investigation of 6-aminonicotinamide as a possible cancer chemotherapeutic agent, after our discovery that this compound is a most potent antagonist of nicotinamide

- 5) a new series of oral hypoglycemic agents (substituted thiazidiazoles) for the treatment of diabetes
- 6) improvement of steroid hormone therapy by inhibiting the conversion of these compounds in the body to the inactive glucuronide form
- 7) preparation of new pharmaceutical dosage forms in which active drugs are adsorbed onto ion exchange resins so as to provide 'controlled release' of the active agent and avoid objectionable tastes and odours, etc."

(Return, May 20, 1960)

(4) Merck

"3. The research and development programme followed three main lines.

- (i) Process Research and Development on processes for production of medicinal and food products by organic synthesis and by fermentation. This included work on Vitamin C, chlorothiazide, hydrochlorothiazide, niacin, corticosteroids, inorganic synthesis and Vitamin B₁₂, penicillin and streptomycin in fermentation synthesis. Development of suitable pharmaceutical forms of these products was carried out.
- (ii) Investigation and synthesis of new classes of organic compounds as potential medicinals and methods of synthesis of isotopically labelled materials for use as chemical and biological tracers.
- (iii) Clinical and field investigations on therapeutic and prophylactic drugs in the human and veterinarian areas.

4. Research expenditures during 1959 including the expense of developing new or improved processes of producing goods was \$189,300 of which \$83,200 was incurred in relation to pharmaceuticals. These figures, however, exclude Research expenses of our parent company which also contributed to the development and improvement of products marketed by our company."

(Return, June 6, 1960)

(5) Parke-Davis

"Subject company does not itself carry on directly any research programs in Canada, nor make direct expenditures or grants therefor. Parke, Davis & Company (its parent company) makes the benefit of its research available to subject company, however, and for 1959 charged subject company \$164,900 as its share."

(Return, June 6, 1960)

(6) Hoffmann- La Roche

"In the Roche world wide organization, basic chemical and pharmacological research is conducted at three main centres: Switzerland, United States and England. The reason for this is obvious: basic research of this type is extremely expensive and efforts must be concentrated rather than dispersed in order that such expense may be controlled and a maximum return (in accomplishment) obtained for the expenditure involved. Our contribution to this overall research program in 1958 was \$74,483.

. . .

Here in Canada, Hoffmann-La Roche Limited undertakes research in the form of clinical evaluation of various new drugs prior to a decision being made as to whether the drug should be marketed. Thus this research is essentially trials in animals and in humans

at various universities and hospital centres and, in later stages, by a large number of eminent practising physicians, which trials in most cases are supported by grants-in-aid from the company."

(Return, May 20, 1960)

(7) Smith Kline & French

"The Company's research program in Canada falls under the direction of the Canadian Medical Director. It involves the clinical investigation of experimental compounds and the laboratory development of new products. Support is also given to outside individuals and institutions in connection with research programs they carry on."

(Return, May 31, 1960)

(8) Poulenc

"Nous n'avons aucun programme de recherches proprement dites au Canada, si on entend à ce propos des recherches ayant pour but de découvrir de nouveaux médicaments. Nos sociétés parentes ou alliées en France, en Angleterre, en Italie, au Brésil, etc. font des recherches de cette nature. Ici au Canada, nous nous contentons de faire expérimenter les produits qui nous sont proposés par ces sociétés. Cette expérimentation comprend notamment des essais de toxicité aiguë et chronique sur les animaux de laboratoire, conformément aux règlements en vigueur. En 1958-59, ces essais ont été faits, à nos frais, dans des laboratoires universitaires, McGill University, Université Laval, Toronto University, Queen's University, Western Ontario University, etc. Nous faisons faire également des essais cliniques par des expérimentateurs qualifiés."

(Return, June 20, 1960)

(9) Schering

"The company undertakes clinical research on all new products, initiating and supporting such research in the hands of independent physicians and medical institutions."

(Return, May 25, 1960)

(10) Ciba

"The Company contributes to the Research activities of its parent Company, such contributions being calculated as a percentage of sales."

(Return, May 20, 1960)

(11) Abbott

". . . All research is done by our parent Company in the U.S.

. . . .

We do employ a Medical Director and staff at a cost last year of \$25,115 to promote the clinical trial in Canada of prospective new products and to recommend grants made by us for Research. . . . New drugs for such trials are supplied without charge by our parent Company."

(Return, June 3, 1960)

(12) British Drug Houses

"Research programme comprises:-

(a) PRODUCT DEVELOPMENT:-

Design, formulation, stability studies and development of control procedures for a wide variety of agents.

- (b) CLINICAL RESEARCH:- This is carried out in collaboration with clinicians in various parts of Canada.
- (c) MICROBIOLOGICAL RESEARCH:- At present confined mainly to field of diagnostics and part to development of assay and control procedures."

(Return, May 20, 1960)

(13) Squibb

"Our Director of Clinical Research works closely with Canadian teaching institutions and universities to help initiate basic research and clinical investigations. Financial grants from the Company are made in conjunction with this work. Work here in Canada is in collaboration with our Corporate Research bases in U. S. A., and other Countries. Our programme calls for a continued expansion of this work."

(Return, June 10, 1960)

(14) Wyeth

"The Company provides financial support, on a selective basis for specific medical research projects initiated by qualified investigators in areas of mutual interest to the investigators and the Company. The objective of such projects is the broadening of medical knowledge in the area selected without direct relationship to Company products.

Financial and/or material support is provided to qualified medical investigators for projects initiated by us to clinically study and evaluate new compounds of potential product interest.

In 1960 the Company inaugurated a programme of an annual unrestricted grant to each of the twelve Canadian Medical Schools. The grant is unrestricted in the sense that its expenditure is administered solely by the Dean of the Faculty of Medicine at his discretion, in support of Medical Research Projects under his jurisdiction.

The Company conducts a continuing programme of product development and improvement. This work is carried on by qualified chemists and technicians in the Company's own laboratories."

(Return, May 27, 1960)

(15) Pfizer

"Pfizer Canada did not itself carry on any research."

(Return, June 14, 1960)

(16) Burroughs Wellcome

"No research programme was carried out in Canada."

(Return, May 24, 1960)

(17) Riker

"Small amount of work was carried out on a product called Deaner (Generic name Deanol), a type of anti-depressant and psychic energiser. . . . was paid for by our parent company."

(Return, May 16, 1960)

(18) Canada Pharmacal

"Continual research is being carried on in the field of product

development. This involves pharmaceutical formulation to provide suitable elegant product and subsequent chemical, physical and clinical tests to ensure continuing stability through normal shelf life of the product."

(Return, May 24, 1960)

(19) Winthrop

"... no basic research is done in Canada. All pharmaceutical research work is done in the Sterling-Winthrop Research Institute in the United States. Here in Canada we conduct clinical studies of some pharmaceuticals during their development stage, prior to their commercial introduction."

(Return, May 20, 1960)

(20) Pitman-Moore

"The present program is divided into two parts

(a) Clinical research. At present the company underwrites directly the cost of a clinical research program in Canada. This involves scheduled visits by our part-time medical director to physicians in teaching centres in Canada. The resulting evaluation of new drugs frequently requires financial support in the form of research grants. For 1960, \$10,600 has been budgetted directly for this program. In addition, approximately 7% of the selling expense budget (approximately \$19,900) is spent in direct support of this work.

(b) Pharmaceutical research. One of the duties of our Canadian laboratory is to develop new formulations of drugs especially adapted to Canadian needs (e.g. climate, and differences in our Food and Drug Act). This is pharmaceutical research and is a continuous element of our program.

...

... A clinical research program was conducted in 1959 but all costs were borne directly by Pitman-Moore Company, Indianapolis."

(Return, May 24, 1960)

213. It should be emphasized that the products of the research of American and other foreign firms are available to these firms' subsidiaries or branches and to other firms where licences are given and so Canadians receive the benefit of research done outside the country as well as of research done in Canada.

214. Various reports have been made on the amount spent by larger drug manufacturers in the United States on research both of the fundamental and applied types. The Kefauver Committee, in Exhibit 160*, gives a breakdown of the sales dollar of the drug operations only of a number of firms for 1958. The following table gives a summary of these figures:

*Hearings, Part 16, p. 9176.

TABLE XXVIII
EXPENDITURES ON RESEARCH

<u>Company</u>	<u>Research Expenditures as Per Cent of Sales</u> %
20 Drug Companies	6.4
Smith Kline & French .	8.9
Carter Products	2.7
American Home Products	3.2
Ciba	13.9

215. Similarly, this Committee gives^x a financial summary of the operations of Merck & Co., Inc. and its subsidiaries for the ten years from 1949 to 1958 inclusive:

TABLE XXIX
MERCK & CO., INC.

<u>Year</u>	<u>Net Sales</u> (Dollars in Thousands)	<u>Research and Development Expenditure</u> ^ø	<u>Research as Per Cent of Net Sales</u> %
1949	110,539	6,614	6.0
1950	139,210	7,042	5.1
1951	171,310	8,315	4.9
1952	160,648	10,001	6.2
1953	160,002	9,863	6.2
1954	145,460	9,651	6.6
1955	157,929	10,504	6.9
1956	172,432	12,540	7.3
1957	186,937	14,512	8.0
1958	206,626	17,091	8.3

^øIncludes process development and product application activities.

Note: All data in the above summary are presented on a fully consolidated basis. Information includes the operations of Sharpe & Dohme, Inc., for the period prior to April 30, 1953, the date of the merger of that company into Merck & Co., Inc.

216. In a report prepared by Karl Bambach, Executive Vice-President of the Pharmaceutical Manufacturers Association, entered as Exhibit 107 to the Kefauver Committee^{xx}, a table is given showing the estimated or budgeted amounts spent directly or indirectly on research, compiled from information given by Pharmaceutical Manufacturers Association members.

^xHearings, Part 14, Table 1, p. 8031.

^{xx}Hearings, Part 17, pp. 9503-5.

TABLE XXX

EXPENDITURES ON RESEARCH

	<u>Estimated or Budgeted</u>	
	<u>1958</u>	<u>1959</u>
1. Amount spent within companies for research and development	\$156,600,000	\$174,700,000
2. Amount spent outside companies for research and development (contracts or grants to universities, hospitals, etc., for specific projects)	13,400,000	15,300,000
Total for research and development	170,000,000	190,000,000
3. Unrestricted grants, contributions, gifts to schools, hospitals, etc., for unspecified purposes, not included above	5,260,000	5,950,000
4. Contributions or gifts to organizations which in turn support medical and related schools (not included above)	1,900,000	2,000,000
Total industry expenditures for research and development, and for medical and related education	177,160,000	197,950,000 <u>[sic]</u>

217. In May 1960, Fortune Magazine published a very informative article* (already referred to) on business strategy in the drug industry in the United States. The author, Mr. Silberman, made many interesting observations about research in the drug industry and the role it plays in competition in that industry. The chart reproduced as Table XXXI is adopted from a chart set out in the article and shows the tremendous expansion in the sales of drugs, particularly of the wonder drugs and other ethical drugs, and shows the expansion in expenditures on research and development. Mr. Silberman says of 'the industry's new technology':

"... The enormous expansion in the industry's spending on research and development - from \$90 million in 1954 to \$190 million last year and over \$200 million planned this year - has given rise to what Schumpeter [Professor Joseph A.] called the 'creative destruction' of old products and old markets at a furious pace. In the drug industry today research is used systematically as a competitive weapon.

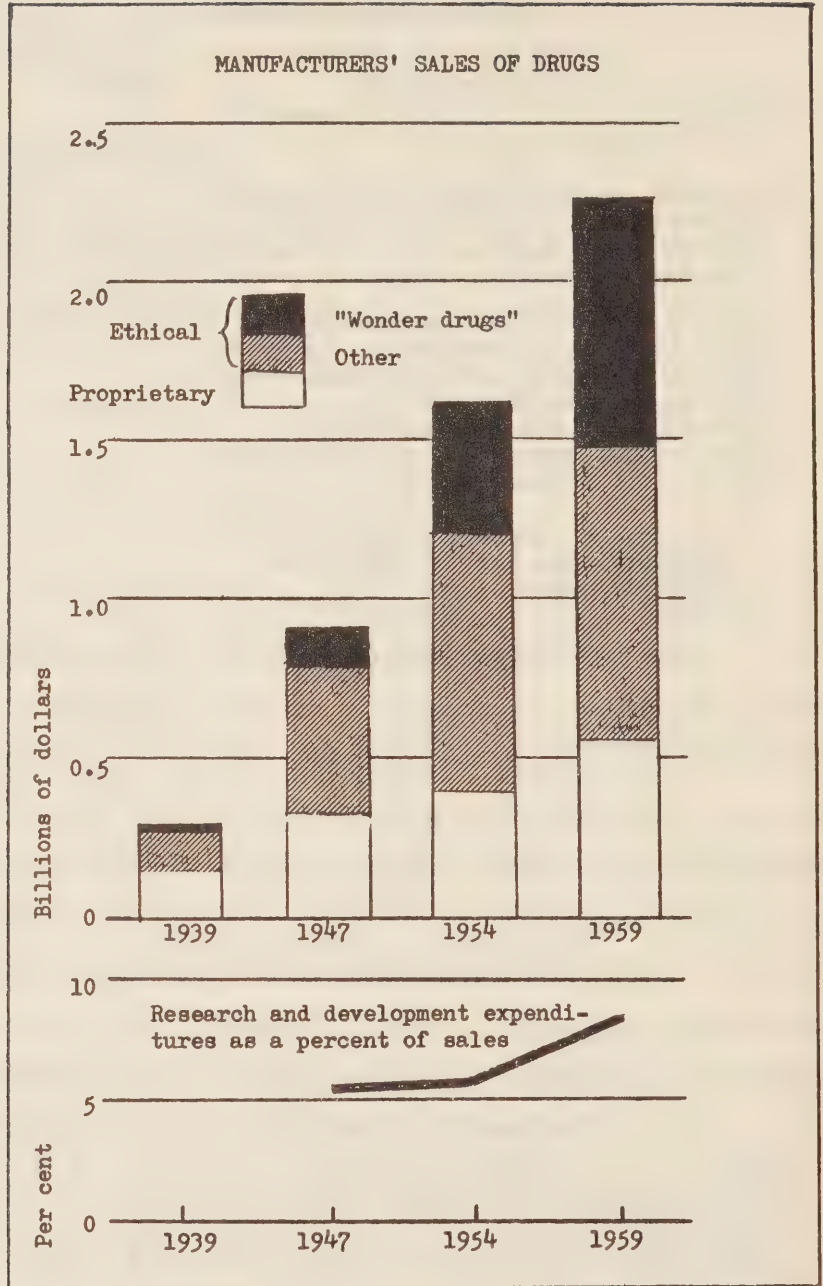
It can be a potent weapon. In a recent analysis of financial data for 1949-58 supplied by some fifty drug companies, the accounting firm of Arthur Andersen & Co. found that research expenditures were a primary factor in determining a company's future share of industry sales. Increasing its share of industry research outlays almost invariably gave a company a higher share of industry sales - and vice versa. The widespread recognition of this fact has been largely responsible for the boom in research spending - a boom in which almost every firm, not just the industry's leaders, is joining.

But the boom is itself altering the impact of research. When every firm uses research to improve its market position, increasing research spending by itself ceases to be such an effective weapon, and the role of marketing assumes a new importance. So does the creativity of the research effort. . . ."

(pp. 138-39)

*Charles E. Silberman, "Drugs: The Pace is Getting Furious", Fortune Magazine, May 1960, pp. 138-41, 269-70, 275-76, 281-82.

TABLE XXXI



"The drug industry has been transformed by research. Back in 1939, sales of drugs at the manufacturers' level came to some \$300 million, with proprietary drugs (advertised directly to consumers) accounting for more than half the total. By 1959, the total had expanded to \$2.3 billion. Most of that growth has been in ethical drugs (advertised only to doctors and usually sold by prescription).

Before 1954, the increase in ethical sales was accounted for primarily by more widespread and intensive use of some familiar old products like vitamins, barbiturates, and laxatives. But in the last five years the so-called wonder drugs--tranquilizers, steroids, antibiotics, etc.--have taken over a much larger share of total sales, partly by creating wholly new markets, partly by moving in on the older markets, as the tranquilizers moved in on the barbiturates. The rise of the wonder drugs is, of course, closely related to the sharp increase in research expenditures (see bottom panel). Sales breakdowns are FORTUNE estimates based on Census Bureau data and figures for 1939 and 1959 supplied by Arthur D. Little Inc."

Source: FORTUNE, May 1960, p. 139

218. The article goes on to identify the various strategies in research pursued by particular companies:

"... Companies whose research has been organized in the interest of maximum growth may be thought of as having 'offensive' strategies; companies interested primarily in preserving existing markets may be thought of as 'defensive.'"

(p. 139)

Merck and Lederle Division of Cyanamid and, to a smaller degree, Pfizer, are given as examples of companies which have highly organized offensive research strategies, with the first two companies tending to specialize in certain distinct fields and the third company doing research in many fields. These companies also are very capable at defensive research. Other companies, such as Abbott, Lilly, Parke-Davis, Wyeth, Schering and Smith Kline & French, are given as examples of companies which have in the past concentrated mainly on defensive research. Broadly speaking, the offensive-research companies have been particularly successful with the newer wonder drugs and tranquilizers, while the defensive-research companies have relied more conservatively on the older, more stable lines of ethical drugs. With the growth in drug sales being predominantly in the fields of the newer types of drugs, the defensive-research companies have not maintained their former share of the expanding market and are going through a period of reappraisal of former policies with many of these companies beginning to engage in offensive research. Mr. Silberman states, in part:

"As the old distinction between offensive and defensive companies breaks down, something like 8 per cent of sales is becoming a 'standard' research expenditure. Furthermore, most companies now appear to be engaged in both offensive and defensive research at the same time. And finally, the old order in the industry has been shaken by the recent tendency of the 'specialty' companies to strive for broad product lines."

(p. 270)

219. Mr. Silberman also suggests that a firm must be offensive not only in the field of research but must extend this attitude to the marketing of the drugs produced by research:

"... there is a tremendous premium just on being first to market with a new drug, for doctors tend to remain loyal to the innovator. Even when a number of other firms come in later with the same generic compound under different names, or with a slightly different compound used for the same purpose, the company that is first can generally count on a dominant share (roughly 40 to 60 per cent) of the market."

(p. 275)

220. While the article just discussed is an evaluation of the American drug industry, it is relevant to an examination of the Canadian industry which in many respects is only an offshoot of the American industry. The question which is posed by this article when the observations made are applied to the Canadian industry is whether it is possible for a Canadian industry to be developed independently of American industry or whether it is inevitable that the Canadian industry will be entirely dominated by the competitive situation in the United States. As an example of the dominant influence the United States can be expected to have in the drug industry, it is interesting to note that Lederle Division of Cyanamid with sales in 1959 estimated at \$160 million (approximately 7 per cent of sales of the industry of \$2.3 billion) is estimated (using figures from the Fortune article) to have spent \$12 to \$16 million on research and to compare this with the total expenditure on research of \$2.0 million reported by the twenty-two Canadian firms listed in Table XXVII. In other words, a single firm in the United States spent approximately six to eight times as much on research as did twenty-two Canadian firms which include the largest in the field in Canada. For the particular firm, Cyanamid, the contrast is even greater. For the year 1959, the parent U.S. company spent one million dollars on research for each one hundred dollars spent on research by its Canadian subsidiary.

221. In summary, the opinion of those research workers who were consulted in the course of the inquiry is that the amount of medical research performed in Canada is relatively limited. The available statistics bear out this opinion. It also appears, from the information obtained, that the outstanding achievements of medical research in Canada have been the result of work done in universities and teaching hospitals.

222. While the Canadian public derives benefit from research done in other parts of the world, notably the United States, and while Canada has contributed substantially to the general knowledge of disease and its treatment, many authorities in the field feel that more should be done in Canada to support and encourage medical research. While other factors are also pertinent, the relationship of most of the large drug manufacturers to parent or related firms in other countries results in the research for such firms being carried on outside Canada. The responsibility of financing

increased research in Canada appears to be regarded more and more as a responsibility of Government and of those private organizations interested in particular diseases.

CHAPTER XIII
QUALITY CONTROL

223. The questionnaire sent to selected firms also asked about the amounts spent on quality control. Quality control in the pharmaceutical industry is intended to satisfy standards of potency, purity and many other factors connected with these standards. An article in the Canadian Pharmaceutical Journal^{*} lists twenty-four possible factors which must be considered when testing drugs. These factors do not appear to be all mutually exclusive and a summary of the factors is probably sufficient to give an idea of the problems of producing a high-quality drug product. Aside from the problems involved in ensuring that each dose of the drug is of equivalent and satisfactory potency and that the active ingredient is of a high standard of purity, the drug manufacturer is concerned with such problems as controlling the release time of the medication, i.e., whether the drug is to be released immediately or over a given length of time; the solubility of the drug, i.e., whether the drug is to be soluble in water, in the stomach or in the intestines; the vehicle or base, i.e., powder, liquid, ointment, etc., and what possible reaction there may be to the ingredients in the base; the packaging of the product; the stability over time of the drug; as well as many other factors.

224. The questionnaires were sent to twenty-seven firms operating in Canada. Six of the firms either did no quality control work in Canada or could not separate quality control expenses from other manufacturing costs. These firms are listed below together with the explanation given concerning the reasons an answer could not be given:

(1) Ames

". . . costs of such operations . . . [are] included in the cost of goods purchased by the Company."

(Return, May 24, 1960)

(2) Dymond

"Routine tests for identity performed by pharmaceutical chemists, along with other duties, and specific cost of these tests not known."

(Return, May 10, 1960)

^{*}"Why Prescription Brand Names are Important", Canadian Pharmaceutical Journal, April 1957, pp. 18-188 to 21-191 and 24-154. (This article is a reprint of the text of a booklet prepared by The National Pharmaceutical Council, Inc.)

(3) Lilly

"All quality control and similar operations are handled by our parent company who subjects each lot to the same exhaustive tests as apply in U.S.A.; locally costs of rigid inspection procedures are part of manufacturing expense and cannot be separated.

(Return, May 24, 1960)

(4) Riker

"Control costs are included in price for finished products and also warehousing etc. charges made to us by Rexall Drug Company.

". . . They are included in cost of material (tablets) which we purchase from Riker Laboratories, Northridge, California. Other control costs are incorporated in finished products purchased from Rexall Drug Company."

(Return, May 16, 1960)

(5) Schering

"Quality Control services are provided free of charge by our parent organization and the value of these services is not known to us."

(Return, May 25, 1960)

(6) Searle

". . . this cost is included and absorbed by the fair market value mark-up of 75% required by Canada Customs for duty valuation."
(See the Chapter on Sales Tax and Tariffs).

(Return, May 26, 1960)

225. Twenty-one firms reported actual or estimated costs of quality control as shown in Table XXXII. These figures are significant chiefly in their relation to the dollar volume of sales of particular firms and this relationship is shown in Table XXIV above. It will be noted that there is little, if any, correlation between the value of sales and the amount spent on quality control. Undoubtedly, the cost of carrying out control over the quality of some drug products is greater than for others. It also appears probable that when machinery and procedures for control have been set up, the cost per unit for testing would decline if a large quantity were handled. Undoubtedly, too, the standard of control exercised varies somewhat from firm to firm. A very important factor is the fact that many branches or subsidiaries import prepared dosage forms of certain drugs in respect of which further expenditures for quality control would presumably be negligible. In any event, whether for these reasons or not, it is clear that the relative costs of quality control vary from firm to firm.

226. The twenty-one firms reporting on expenditures for quality control

[Note: Table XXVII, showing expenditures by individual companies on research, and Table XXXII, showing expenditures by individual companies on quality control, have been omitted from the copies of the Statement being distributed because they would provide a key to the identity of the companies listed by letters in Table XXIV above. The tables are included in the copies of the Statement supplied to the Commission.]

in Canada reported spending a total of \$1,124,858 in the year for which the report was made (generally 1959). Total sales for these firms were \$93,016,127. That is, on the average, for every dollar of sales, 1.21 cents was spent on quality control. Elsewhere in this inquiry, it was estimated from information received from twenty-two firms operating in Canada that the cost of goods sold was 33.38 per cent of net sales. Applying this figure to the percentage of net sales spent on quality control, it can be estimated that quality control is approximately 3.62 per cent of the cost of goods sold. It will be realized, of course, that these calculations are based on information obtained from selected firms. Nevertheless, because these firms include the most important firms in the drug industry in Canada, the figures shown should afford a fairly reliable guide to expenditures on quality control.

227. Various other estimates have been made of the amount spent on quality control. Dr. Arthur Grieve, Director of Control for Ayerst, is quoted as saying that quality control amounts to less than 10 per cent of the cost of manufacturing a drug in Canada (Vancouver Sun, April 12, 1960). The Canadian Pharmaceutical Manufacturers Association, "comprising some 60 members which do about 90 per cent of the ethical pharmaceutical manufacturing business in Canada" states:

" . . . According to some manufacturers, these painstaking, comprehensive quality safeguards are responsible for from 10 to 15 per cent of production costs. . . ."

(Facts about Pharmaceutical Manufacturing,
Canadian Pharmaceutical Manufacturers
Association, p. 3.)

CHAPTER XIV
PROFITS OF DRUG FIRMS IN CANADA

228. During the inquiry, financial statements were obtained from 144 firms. Most of these firms were ethical drug firms but the number included some proprietary drug firms, wholesalers, and manufacturers of basic drugs and chemicals (i.e., firms which manufacture basic drugs and chemicals for sale to other manufacturers which prepare dosage forms for sale to the public). As already noted, firms in the drug field are difficult to categorize precisely. Even firms whose main business is ethical drugs usually carry some proprietary drugs and related lines and vice versa. Wide use is made of national distributors and certain firms which manufacture their own lines are also important as distributors of the products of other firms. In the proprietary drug field, a firm may manufacture and distribute not only proprietary drug items but toiletries, cosmetics, or similar lines as well. It is therefore extremely difficult to classify firms except in a very general way.

229. Firms vary widely in size. The largest sales reported by any firm were in excess of ten million dollars per year. From this high, reported sales ranged down to a few thousand dollars. Certain firms, of course, have large sales in other fields. The Medical Products Division or Lederle Division of Cyanamid is one of the large firms in the drug field, but this Division only accounts for a small percentage of Cyanamid's total sales. Such firms as Ingram & Bell, Hartz, or Herdt & Charton reported sales ranging up to half a million dollars in the drug field, but their main businesses are in surgical supplies.

230. In the case of some firms, it is not possible to separate their operations in the drug field from their overall operations. Apart from these, the following firms appear to have sales, principally in the ethical drug field, in excess of one million dollars:

Abbott
Anca
Ayerst
Baxter
Bristol
British Drug Houses
Burroughs-Wellcome
Ciba
Frosst

Geigy
 Horner
 Lilly
 Merck
 Merrell
 Nadeau
 Ortho
 Parke-Davis
 Pfizer
 Poulenc
 Robins
 Rougier
 Schering
 Smith Kline & French
 Squibb
 Upjohn
 Warner-Chilcott
 Winthrop
 Wyeth.

Profits before taxes, as a percentage of sales,*as reported by these firms, ranged from 37.79 per cent to a loss of 1.2 per cent. (This loss was reported by a subsidiary of an American company. The parent company reported a profit, presumably including the operations of the subsidiary, before taxes of over 10 per cent - the exact figure cannot be given without identifying the company). The distribution of profit rates was as follows:

<u>Profit Rate</u>	<u>Number of Firms</u>
30% and over	- 1
20% to 30% .	- 12
10% to 20% .	- 6
0 to 10% ...	- 8
loss	- 1

The total net sales of the 28 firms were \$104,183,958 and total profits before taxes were \$17,758,462 which works out to a profit before taxes of 17.08 per cent.

231. The majority of the large firms in the ethical drug field are subsidiaries or branches of foreign firms, particularly American firms. In some cases, it is not practical to compare earnings of the subsidiary with those of the parent for various reasons. Ayerst and Wyeth, for example, are subsidiaries of American Home Products Corporation. But while the former are ethical drug firms, the latter carries on business in many fields. Of the 28 firms mentioned above, the following are branches or subsidiaries of firms which carry on ethical drug businesses in the United States for which information on earnings is available:

Abbott	Merck
Baxter	Parke-Davis
Lilly	Pfizer

*Profit as a percentage of sales rather than as a return on investment has been shown because of the difficulty of obtaining accurate information about the latter.

Schering
Smith Kline & French
Upjohn

The average rate of profit before taxes for these companies on their Canadian operations was 15.68 per cent. The average rate of profit before taxes for the American parents of these firms was 24.98 per cent. In only one instance was the rate of profit for the Canadian branch or subsidiary higher than for the respective United States parent company. (The figures given are averages of the rates for individual firms rather than a computation based on total profits as a per cent of total sales.)

232. It has not been possible, on the information available, to make any accurate assessment of profits of firms in the proprietary drug field. Some indication of such profits is afforded by the returns of four large firms:

Miles Laboratories (Alka-Seltzer, One-a-Day Vitamins, etc.)
Harold F. Ritchie* (Eno Fruit Salts, Scott's Emulsion,
Brylcream, etc.)
Sterling Drug (Bayer Aspirin, Phillips Milk of Magnesia, etc.)
Whitehall Laboratories (Anacin, Heet Liniment, etc.).

Profits on sales reported by these firms ranged from 7.25 per cent to 20.44 per cent before taxes. On total sales of \$17,734,377, reported profits before taxes were \$2,250,076 or 12.69 per cent. For various reasons, it is impossible, on the available information, to make any meaningful comparison between rates of profit in the proprietary drug field in Canada and in the United States.

233. Several general statements have been made from time to time concerning the profitability of the drug industry in various countries and relative to profits in other industries.

United States of America

234. Statistics compiled by the Federal Trade Commission indicate that the manufacturing of drugs is profitable relative to other types of manufacturing. Table XXXIII sets out the figures given for the drug industry and several other manufacturing industries. The profits referred to are net profits taking into account capital gains and dividends received, capital losses and depletions, and adjusting for international flows affecting profits.

*The name of this company, which is a wholly-owned subsidiary of Beecham Overseas Limited, England, has been changed to Beecham Products Limited. It is operated in association with Beecham Research Laboratories Limited. Together these firms offer products ranging from toothpaste to the most recently developed penicillins and illustrate the difficulty of classifying firms.

TABLE XXXIII

PROFITS PER DOLLAR OF SALES, BY INDUSTRY (CENTS)

<u>Industry</u>	<u>Before Federal Income Taxes</u>				
	4th Qr. <u>1958</u>	1st Qr. <u>1959</u>	2nd Qr. <u>1959</u>	3rd Qr. <u>1959</u>	4th Qr. <u>1959</u>
All manufacturing corporations, except newspapers	8.6	8.9	10.2	8.2	7.9
<u>Durable Goods</u>	9.4	9.7	11.7	7.7	7.9
Transportation equipment	9.5	11.5	12.1	5.9	6.7
Electrical machinery, equipment and supplies	9.0	8.2	9.1	9.0	9.3
Other machinery	8.1	7.9	11.5	10.4	8.4
Other fabricated metal products	6.5	5.6	7.6	8.0	4.6
Primary metal industries	12.7	13.3	15.5	-0.3	8.6
Stone, clay and glass products	12.8	11.7	17.7	16.5	11.8
Furniture and fixtures	6.2	4.3	5.5	6.5	4.7
Lumber and wood products, except furniture .	6.3	5.6	8.5	8.7	5.3
Instruments and related products	13.1	11.9	12.6	14.5	13.0
Miscellaneous manufacturing and ordnance ...	6.8	5.9	5.9	9.2	7.6
<u>Non-Durable Goods</u>	7.8	8.0	8.6	8.6	7.8
Food and kindred products	4.7	4.5	4.9	5.3	4.9
Tobacco manufactures	11.6	10.9	11.5	11.8	10.7
Textile mill products	4.4	4.9	5.8	5.7	6.2
Apparel and other finished products	2.3	3.1	2.9	3.3	2.6
Paper and allied products	10.0	9.7	11.0	10.2	9.8
Printing and publishing, except newspapers .	4.9	7.0	8.0	9.4	6.1
Chemicals and allied products	13.5	14.6	15.9	15.5	13.2
Basic chemicals*	15.4	17.1	19.2	17.4	16.1
Drugs*	19.2	20.7	18.6	22.5	17.0
Petroleum refining and related industries ..	12.0	10.9	10.5	10.6	11.1
Rubber and miscellaneous plastics products ..	7.8	8.1	8.7	7.7	6.8
Leather and leather products	4.2	4.1	4.9	4.6	4.6

*Included in major industry above.

Source: Federal Trade Commission, Securities and Exchange
Commission, Quarterly Financial Report for Manufacturing
Corporations, Fourth Quarter 1959.

235. Table XXXVIII indicates quite clearly that basic chemicals is the only strong contender for first place, with stone, clay and glass products occasionally making attempts to enter the contest.

United Kingdom

236. Gross profits as a percentage of total assets in certain manufacturing industries for the United Kingdom for 1954 indicate the following:*

All manufacturing	15%
Drugs and toilet preparations	39
Paint and varnishes	31
Soap, etc.	23
Rayon, nylon, etc. production	22
Tobacco	38
Biscuit	30
Cocoa, chocolate, etc.	27
Bread, etc.	22

237. Comparing gross profits in various industries suffers from the disadvantages of not giving attention to differences in cost of production, distribution, packaging, etc., in the industries.

238. In the Civil Appropriation Accounts Report for 1958-59^{xxx}, the following passages appear:

"30. Departmental accountants have calculated from the published accounts of 43 pharmaceutical firms the percentages of profits earned on capital employed for the years 1951 to 1957. The accountants stress, in their report, that the figures must be subject to very important reservations which arise from the inadequate information available from published accounts. Moreover, such accounts relate to the whole activities of the companies, many of whom have important business not connected with the National Health Service. Consequently any conclusions drawn from the figures should be on broad lines and relate to the general position and trends in the industry rather than to the National Health Service alone, or to the position in respect of proprietary preparations supplied thereto. With these reservations their broad conclusion was that the profits of these companies, expressed as percentages of capital employed, had been above those of general industry throughout the period examined and had lately tended to increase whereas the rate for general industry had been falling. While the position varied greatly between individual manufacturers and groups of manufacturers it was noticeable that the profit rates of the British subsidiaries of American concerns had consistently been much higher than those of general industry.

31. The accountants' report states that the computed profit rates of some of these subsidiaries may be understated owing to lack of information about the extent of capital expenditure not yet productive. On the other hand it is probable that the profit rate of some of them is higher than it would otherwise be because they receive free of charge the benefit of administrative and research services from their parent organisations in America. . . ."

*J. D. Hughes and K. Alexander, "The Control of Profit and Inflation in the United Kingdom", Cartel, Volume 9, No. 4, October 1959, p. 131.

^{xxx}United Kingdom, Civil Appropriation Accounts (Classes I-V) 1958-59, pp. ix-x.

Canada

239. A series of profit rates for various types of manufacturing industries in Canada for 1958 has been compiled from Taxation Statistics^{*}. The following are the reported profit rates for various industrial classifications and for the pharmaceutical manufacturing industry for the 1958 taxation year:^{**}

<u>Manufacturing Industry</u>	<u>Profit Rate</u>
	%
Foods and beverages	5.6
Tobacco and tobacco products	7.9
Rubber products	6.3
Leather products	1.0
Textile products (except clothing)....	4.2
Clothing	2.5
Wood products	2.7
Paper products	10.8
Printing and publishing	7.3
Iron and steel products	7.2
Transportation equipment	5.9
Non-ferrous metal products	2.8
Electrical equipment	5.3
Non-metallic mineral products	10.1
Petroleum and coal products	3.1
Chemical products	7.0
pharmaceuticals ^{xxx}	10.5
Miscellaneous manufacturing industries	6.4
All manufacturing industries	5.9

240. On the basis of these figures then, the manufacturing of pharmaceuticals in Canada shows a greater profit on sales than the manufacture of most other products. The exception is the manufacture of paper products. The manufacture of non-metallic mineral products is the next most remunerative.

241. While it is impossible, on the basis of the figures given here, to conclude whether the preparation of drugs is more profitable in one country than in the other two, it is possible to say that it appears that, in each of the three countries, the manufacture of drugs is a relatively profitable line of manufacturing.

^{*}Canada, Department of National Revenue, 1960 Taxation Statistics, Section III, Table 4. The profit rates are "Current Year Profit" (before taxes) expressed as a percentage of "Total Revenues" which include as well as sales, rents and dividends received. The figures include revenues and net profit (or loss) of both profit and loss companies.

^{**}Op cit., p. 92.

^{xxx}Included in the group total preceding.

CHAPTER XV

COSTS AND SELLING PRICES OF CERTAIN DRUGS AT THE MANUFACTURERS' LEVEL

242. In this chapter the costs of certain drugs and the markups taken by manufacturers are discussed. These markups are not profits since the cost of manufacturing or purchasing goods for resale is only one of the costs of doing business. Because of conditions peculiar to the industry, the importance of research, the fact that ethical drugs are not advertised to the public but are promoted by detail men and by direct mail advertising to doctors and pharmacists, the practice of distributing samples, and similar factors, costs other than direct costs of manufacture are important.

243. For the drugs listed below, costs are indicated in two ways. Where the drug is purchased in a prepared dosage form, as when a firm imports the prepared product ready for resale from its parent company, this cost is shown. In such cases it is possible to make a direct comparison between cost and selling price. As already pointed out, the difference is not profit; it is simply the markup over prime cost. How much of this markup the firm is able to retain as profit depends on its other expenses of doing business.

244. Where the drug is purchased in bulk, the cost of the basic drug is given and the cost of the theoretical amount of the drug required to prepare a particular dosage form is given so that some basis of comparison is supplied. It should be remembered that the quantity is theoretical because it does not allow for wastage, the necessity of using extra quantities of the drug to ensure that each dose will be of at least minimum specifications, and similar factors. In other words, in practice it may not be possible to take one billion units of penicillin and produce one thousand doses of one million units each, or to take 100 grams of a drug and produce 400 tablets of 250 mg. each. It is likely to take slightly more of the basic drug than the precise theoretical amount required. The overage will depend on the nature of the drug, its stability, the type of dosage form being prepared, and similar factors. Moreover, there is the cost of preparing the dosage form and of packaging it. In the returns of information submitted in 1958, the firms submitting returns gave the cost of the basic drugs which they purchased or manufactured and the cost of preparing dosage

forms. It appears obvious from an analysis of these returns that either costs vary rather widely from company to company, or that different factors are considered by different companies in calculating costs. For example, Ayerst and Wyeth both reported purchasing meprobamate at the same price from Fine Chemicals, but one reported the cost of preparing 50 tablets of 400 mg. each as almost double the cost reported by the other.

245. It seems clear that the cost of preparing tablets or capsules is very small and is insignificant as an element of total cost. Presumably, certain special tablets and capsules, as for example timed disintegration types, cost slightly more to prepare. The cost of preparing solutions or suspensions is not too clear, but appears to be low. Ampoules of a drug in solution for injection appear to be a more expensive type of dosage form to prepare. One firm which prepared ampoules of reserpine in 2 c.c. and 10 c.c. ampoules reported its direct costs and, taking out the cost of the basic drug, the costs of preparing the ampoules would be 3.06 cents for the 2 c.c. size and 5.84 cents for the 10 c.c. size. On the other hand, Merck sold procaine penicillin G to drug manufacturers at 3.3 cents to 3.8 cents per million units, depending on the quantity purchased, while it sold the custom-labelled 10 c.c. ampoule of three million units of procaine penicillin G in aqueous suspension to other manufacturers at 42 cents. This means it was charging about 30 cents over and above the theoretical cost of the penicillin for preparing and labelling the 10 c.c. ampoule. However, even in this case, the cost of preparation was only three cents per c.c. (a common dose).

246. Packaging and labelling a dosage form are relatively more expensive for small packages. One manufacturer gave complete figures which illustrate this. This firm purchased a basic drug at \$126.34 per kg. It prepared tablets at a total cost for the tablets in bulk which would work out to \$151.84 for one kg. of the drug in tablet form. The tablets were then packaged into packages of 50, 500 and 5,000. The cost of packaging was reported to be as follows (per thousand packages of each size):

<u>Size</u>	<u>Tablets</u> \$	<u>Finishing Supplies</u> \$	<u>Direct Labour</u> \$	<u>Manufacturing Overhead</u> \$	<u>Total Cost Per Thousand</u> \$
50's	54.90	57.27	13.38	28.77	194.32
500's	949.00	76.38	27.79	59.75	1,112.92
5,000's	9,490.00	213.42	66.35	142.65	9,912.42

It will be noted that the cost of packaging one thousand packages of 50 tablets each was only \$99.42, but this more than doubled the cost of the tablets. By contrast, the cost of preparing one thousand packages of 5,000 tablets each was \$422.42, but this added only about 4½ per cent to the cost of the tablets.

247. The same firm paid from six to slightly over eight cents, exclusive of the cost of the drug, for the preparation, labelling and packaging of 2 c.c. ampoules.

248. It is clear that in the case of very cheap basic drugs the cost of preparing the dosage form and of packaging it may be higher than the cost of the drug itself. Thus, even at Merck's selling price, common penicillin costs only slightly over three cents for one million international units and is available at an even lower price to some firms which manufacture the drug or obtain it from their parent company. On this basis, the penicillin required for 12 tablets of 50,000 I.U. (i.e., 600,000 I.U.) would cost about two cents; but the total cost of preparing and packaging such a dosage form appears to range around 16 cents to 25 cents.

249. The cost of preparing a dosage form and the cost of packaging appear to fluctuate only within small limits. Tableting or capsuling one drug is essentially the same as tableting or capsuling another and although such costs as quality control may vary, presumably the same firm will exercise the same standard of care in preparing tablets of potassium penicillin G as in preparing tablets of penicillin V. Bottles and labels of the same size cost the same regardless of whether they are used for a cheap drug or an expensive one.

250. In the result, the cost of preparing and packaging cheaper drugs tends to inflate the cost of preparing dosage forms of these drugs. As the cost of the basic drug increases, the cost of preparing and packaging dosage forms becomes less significant in the total cost. Conversely, because preparing and packaging costs tend to be standard, the cost of a dosage form will not increase in direct proportion to the cost of the basic drug.

Thus, to use hypothetical figures, assume the preparing and packaging of a quantity of tablets cost one dollar and the basic drug one dollar for a total cost of two dollars. Now, if another drug costing two dollars is prepared and packaged in the same form, the cost of the basic drug has doubled, but the total cost has only increased from two dollars to three dollars. The same trend will be apparent as long as cost of preparation and packaging is significant in relation to the cost of the basic drug. However, in the case of an extremely expensive drug, the packaging cost would be insignificant and the cost of the prepared dosage form would tend to reflect the cost of the basic drug.

251. One other point should be noted. When a drug is purchased by a Canadian subsidiary from a foreign parent, the price at which the Canadian subsidiary buys is its cost. But the price may be an arranged price in the sense that it is not the same price that would be charged if the parent was dealing at arm's length with an independent firm. The price may represent only prime cost of manufacture or, on the other hand, it may be artificially high. It was not feasible for the Director to attempt to determine the basis on which a foreign firm establishes its costs on a particular drug and, in the case of many drugs, there is no established open-market price for the drug at the manufacturer's level.

252. The prices of the simpler dosage forms only are shown. These reflect the lowest costs of preparation and packaging and can most easily be related to the cost of the basic drug. Combinations of drugs are more costly to prepare and it is difficult to relate these costs back to costs of the individual drugs used in their preparation.

253. Some firms forwarded price lists showing list or suggested resale prices and prices to various classes of buyers. Others only supplied list prices or prices to some classes of buyers, but gave the discounts applicable to other classes of buyers. For this reason, it has been necessary to calculate certain prices and, when this was done, the price is marked with an asterisk (*). In some cases, while it was stated that prices charged to public hospitals were on a trade price less sales tax basis, only a tax-included price was shown. These prices are marked "STI" (sales tax included). On sales to tax exempt hospitals, prices so marked would be reduced by the amount of the sales tax, approximately 10 per cent.

254. Prices shown are regular prices. Almost all manufacturers offer special prices, free goods or additional discounts or rebates on purchases of specified quantities of particular drugs or on consolidated purchases totalling a certain amount. These vary from firm to firm and from product to product for the same firm. Thus, a certain proportion of sales are made at prices different from those shown, but it would be impractical to try to set out the details of all special prices.

255. In the costs and selling prices given below, costs and selling prices of all firms are not listed where there are a large number of firms dealing in a particular drug. When, as is sometimes the case, the same or similar dosage forms of a drug are sold by large manufacturers at one price level and by small manufacturers at another price level, examples of each level of prices are given. The examples are representative, although there may be minor differences in the prices of each group of manufacturers. One source of such differences was the increase in sales tax from 10 per cent to 11 per cent. Thus, before the change the list price of the 16 capsule package of 250 mg. capsules of each of the four broad-spectrum antibiotics was \$9.35. Each manufacturer showed this price. After the increase in sales tax, prices were increased by some manufacturers to \$9.43, by others to \$9.44 and by still other manufacturers to \$9.45. On other drugs, some manufacturers did not add the increased sales tax to the prices of certain dosage forms, while other manufacturers did. In the result, list prices of similar products which were formerly identical now vary by a few cents. Examples of this will be noted among the prices set out below.

Penicillin

256. There are several types of penicillin. They can be roughly classified as "old" and "new" on two grounds. First, old penicillins are virtually free of patent control, while new penicillins are subject to patent control. Second, there are differences in therapeutic qualities. It is claimed that the newer penicillins are effective for longer periods and that results can be obtained by oral administration in the case of the newer penicillins which can only be obtained by injection in the case of the older penicillins. However, according to some medical authorities, the older penicillins are still the drugs of choice in many situations.

Whatever may be the validity of the claims made for the new penicillins, it is certainly not the case that the older penicillins have been supplanted by newer and better forms and "old" is not used here with that connotation. It appears that each type has its place and either may have advantages, depending on the circumstances.

257. The older forms of penicillin include potassium, sodium and procaine penicillin G. These drugs are manufactured in Canada, but a number of firms obtain their supplies from their parent or affiliated companies outside Canada, while other firms import from various other sources. Merck appears to be a large supplier of other Canadian manufacturers and particularly of smaller firms which buy prepared dosage forms ready for resale. Penicillin is widely sold in dosage forms in which it is combined with other drugs. Common dosage forms of the drug itself include tablets, vials with or without a diluent, and prepared solutions for injection of penicillin in aqueous suspension, in oil or in oil with aluminum monostearate. The strength of a dosage form is usually indicated in international units of potency, commonly abbreviated "I.U." or simply "MU" for one million international units and "BU" for one billion international units. Strength varies from type to type, but for potassium penicillin G, one kg. equals about 1.565 BU.

258. The cost of the several types of older penicillin is usually identical. Prices paid by firms importing these drugs from parent or related companies ranged between \$23.00 and \$77.00 per BU. (One firm reported a price of \$83.17, but the average price which it paid was apparently much lower.) Firms importing from foreign sources reported prices of about \$28.00 per BU. Merck sells the three types of penicillin mentioned to other manufacturers at from \$33.00 to \$38.00 per BU, depending on the quantity purchased.

259. An interesting point about the price of penicillin has been its steady decline which has continued up to the present. Prices in Canada for earlier years are not available, but presumably they would be slightly above those current in the United States. The following table shows prices from 1947 to the end of 1956 in the U.S. (as given in the FTC Report) and in Canada from 1954 to 1959 as reported to the Director by Merck. As this table is

intended only to illustrate the trend, the prices shown are for purchases of 25 BU or the closest quantity thereto for which a price was quoted and prices for other quantities are omitted. It is pointed out in the FTC Report that the prices shown are catalogue prices and that actual sales prices may, on occasion, have been lower.

PENICILLIN - PRICE PER BU

	<u>U.S.</u> <u>\$</u>	<u>Canada</u> <u>\$</u>
January 1947	2,500.00	
July 1948	1,250.00	
December 1948 ...	900.00	
March 1949	700.00	
July 1949	575.00	
August 1949	525.00	
January 1950	450.00	
January 1952	250.00	
January 1953	90.00	175.00
January 16, 1953.		160.00
March 18, 1953 ..		125.00
October 22, 1953.		96.00
June 1954	80.00	
August 3, 1954 ..		80.00
November 10, 1954		65.00
May 1955	55.00	
August 15, 1955..		50.00
October 3, 1955..		45.00
June 1956	51.00	
August 1956	56.00	
November 1956 ...	63.50	
December 4, 1956.		60.00
March 20, 1957 ..		65.00
June 7, 1958		62.50
December 15, 1958		55.00
April 30, 1959 ..		38.00
August 24, 1959 .		33.00

260. Information supplied to the Director indicated a wide variation in the cost of prepared dosage forms. One of the smaller firms imports finished tablets from the United States at the following prices per hundred tablets (in U.S. funds and not including duty):

50,000 I.U. tablets per 100	\$0.35
100,000 " " " "	0.60
200,000 " " " "	1.00
250,000 " " " "	1.25
500,000 " " " "	2.50

One packager in Canada sells 500,000 I.U. tablets to various small drug firms for \$28.50 per thousand. Presumably, packaging costs would have to be added. Information submitted in 1958 by the large ethical drug firms showed a variety of costs for packaged tablets (these costs covered both

manufactured and purchased products). The following are examples:

50,000	I.U.	packages	of 12	\$0.17	-	\$0.34
"	"	"	" 100	0.59	-	1.42
100,000	"	"	" 12	0.16	-	0.32
"	"	"	" 100	1.13	-	1.50
200,000	"	"	" 12	0.20	-	0.23
"	"	"	" 100	1.12	-	1.42
500,000	"	"	" 12	0.43	-	0.69
"	"	"	" 100	2.93	-	5.56

The cost of penicillin is now lower than in 1958 so presumably these tablets would now cost slightly less to prepare.

261. The 1,000,000 I.U. vial may be taken as an example of penicillin in vials. Costs of prepared and packaged vials as reported to the Director varied from 21 cents to 30 cents for most firms.

262. A widely used dosage form is the 10 cc. size containing 3,000,000 I.U. of procaine penicillin G for injection. The penicillin may be in aqueous suspension, in oil, or in oil with aluminum monostearate. Costs are roughly the same for all three forms. Merck sells this prepared dosage form to other manufacturers at 42 cents. (Special contracts may provide for a slightly lower price). This appears to be very close to the cost of manufacture and may be taken as the typical cost of this dosage form.

263. Prices of dosage forms of the older penicillins appear to have been in a state of flux at the time the latest information was gathered, perhaps reflecting the changes in the cost of penicillin. Information gathered in 1958 showed that prices charged by the large established firms for similar dosage forms were either identical or varied within a small range. Smaller manufacturers or distributors frequently showed a lower price if they handled an equivalent dosage form. The latest information showed a variation in the prices charged by the large established firms and appeared to indicate that price reductions were being made in the industry, but had not yet been adopted by all firms although they probably have or will be. For example, the earlier information showed that Abbott, Ayerst, Lilly, Parke-Davis, Pfizer, Squibb, British Drug Houses and Winthrop all listed a 1,000,000 international unit vial of sodium or potassium penicillin G at 88 cents. In later information, Abbott, Ayerst, British Drug Houses and Squibb showed a list price of 65 cents, while Lilly and Parke-Davis continued to show 88 cents. Pfizer showed 89 cents, probably reflecting an adjustment made when the sales tax was increased. The

catalogue supplied by Winthrop did not list this dosage form. It appears obvious that there was a general trend to a new price of 65 cents for this dosage form which has or will probably be followed by those firms which have not yet changed. The same thing appears to be happening with respect to other dosage forms of the older types of penicillin.

264. Typical prices of various dosage forms of the older penicillins are set out below. Unless otherwise noted, the hospital price is the regular hospital price and not the lowest price available on purchases of large quantities.

Tablets - 50,000 I.U.

		<u>Size</u>	<u>List</u> ↓	<u>Retailer</u> ↓	<u>Hospital</u> ↓
Abbott	Abbocillin	12's	1.00	.60	.55
Bio-Chemical ..		"	1.20	.72*	
Jamieson	Jacillin	"	1.02	.55	
Abbott	Abbocillin	100's	8.10	4.86	4.36
Bio-Chemical ..		"	8.65	5.19*	
Dymond		"	3.00	1.50*	
Empire		"		1.85	
(as shown in Dominion Pharmaceutical Co. price list.)					
Abbott	Abbocillin	250's	19.55	11.73	10.56
Dymond		500's	12.50	6.25*	
Dymond		1,000's	24.00	12.00*	

Tablets - 500,000 I.U.

Ayerst	Hylenta	12's	4.05	2.43	2.19
Bell-Craig		"	3.83	2.30*	
Bristol	Palacillin	"	4.00	2.40*	2.16*
B.D.H.		"	3.10	1.86*	1.67*
McClung Clemens		"	2.25	1.35*	
Ayerst	Hylenta	100's	30.30	18.18	12.60
Bristol	Palacillin	"	29.76	17.85*	16.07*
B.D.H.		"	24.10	14.46*	12.60
Empire		"		10.00	
Ayerst	Hylenta	500's	141.40	84.84	41.00
Dymond		"	110.00	55.00*	
Empire		"		45.00	

Vials - 1,000,000 I.U.

Abbott65	.39	.35
Ayerst65	.39	.35
B.D.H.65	.39*	.39 STI
Glaxo-Allenbury		.65		
Lilly88	.53*	
Merck35
Pfizer65	.39*	.35
Parke-Davis88	.53	.35
Squibb65	.39	.35

Injectable - 10 cc., 300,000 I.U. per cc. (Prices shown are for aqueous suspension)

	<u>List</u> \$	<u>Retailer</u> \$	<u>Hospital</u> \$
Abbott	1.85	1.11	.82
Ayerst	1.50	.90	.81
Squibb	1.50	.90	.81
Gilbert	2.00	1.00	.80

265. Prices to Departments of the Federal Government have been much lower than regular trade prices. On the 500,000 I.U. tablets in packages of 100 tablets, the following tenders were submitted in November 1959 (the quantity involved was 960 bottles of 100):

Bell-Craig ...	\$2.085 per 100
Winley-Morris .	2.10 " "
Gilbert	2.10 " "
Mowatt & Moore.	2.31 " "
Squibb	3.00 " "
Horner	3.20 " "
B.D.H.	3.65 " "
Glaxo-Allenbury	3.98 " "
Bristol	5.34 " "

For vials of 1,000,000 I.U. of penicillin G sodium crystalline, the following tenders were submitted in December 1959 (on a requirement of 10,800 vials):

Gilbert	\$0.14 per vial
Glaxo-Allenbury	.15 " "
Merck185 " "
Squibb24 " "
Lilly40 " "

For 10 cc., 3,000,000 I.U. procaine penicillin G in aqueous suspension, on relatively small requirements ranging from 50 to 1,200 vials, Merck quoted 25 to 26½ cents, Pfizer 25 to 28 cents, Fine Chemicals 48 cents and Bio-Chemical 52 to 75 cents.

266. On the basis of available information about costs, and allowing for any savings on direct sales to Government Departments, it is clear that many of these sales were at prices close to or even below actual cost.

267. The following points may be noted about the price of dosage forms of the older penicillins:

- (a) Small tablets in small sizes are relatively more expensive than larger tablets and larger sizes. Thus, in the package of 12 of the 50,000 I.U. size of Abbott's Abbocillin, the retail price works out to \$1.67 per MU as against \$0.67 per MU for 12 of the 500,000 I.U. size (Ayerst, Hylenta). A comparison between 12 of the 50,000 I.U. size and 500 of the 500,000 I.U. size shows comparative prices of

\$1.67 and \$0.57. A comparison which probably has more significance is one between the list price of the small package, which a purchaser at a drug store would pay (plus any prescription fee), and the price of a large quantity to a hospital. It will be noted that the price of 500 Ayerst Hylenta tablets, 500,000 I.U. size, to hospitals is \$41.00 (and on large quantities is as low as \$36.50). Taking the hospital price as \$41.00, while a purchaser in a drug store would pay at least \$1.67 per MU for the 50,000 I.U. size in a package of 12 and \$0.67 per MU in the 500,000 I.U. size, a hospital would pay \$0.16 per MU in the 500,000 I.U. size.

(b) The prices charged by small firms (Dymond, Empire above) are significantly lower than those of the larger firms in the case of tablets.

(c) The manufacturers' markups over cost on the 1,000,000 I.U. vial dosage form are low. As noted, costs appear to range between 21 cents and 30 cents and the usual price to hospitals is only 35 cents.

(d) Similarly, the manufacturers' markups over cost on the 10 cc. injectable form are also low. It will be noted that, as in the case of the previous item, special prices to hospitals were in effect even before the recent reductions in list price. Prices even lower than those set out are allowed on quantity purchases.

(e) Unlike prices of certain other drugs which will be referred to below, prices of dosage forms of penicillin have fluctuated not only in the initial period (when this would be expected because of greatly improved methods of production), but down to the present. Prices and the dates of price changes varied from firm to firm, but the following example will illustrate the trend:

Suggested list prices of penicillin G procaine, 10 cc.,
3,000,000 I.U. as reported by Lilly

(Introduced) April 1948.....	\$23.40
July 1949	14.40
September 1949 ...	11.60
February 9, 1950 .	9.85
April 10, 1951 ...	10.00
September 10, 1951	7.85
December 17, 1951.	5.96
March 25, 1952 ...	3.08
October 25, 1954 .	1.83
March 21, 1957 ...	2.24
January 24, 1958 .	1.83
September 23, 1959	1.50.

(f) In summary, basic penicillin is now a low-priced drug.

When purchased in small packages and in dosage forms of small quantities per dose (as would presumably be called for in the usual prescription), it is relatively more expensive, but this probably reflects the cost of preparation and packaging. It is a common statement in the industry that the package now costs more than the penicillin and this is obviously true. Present prices of both the basic drug and prepared dosage forms appear to result from the absence of patent control which has meant that the drug has been freely available to all firms wishing to deal in it. Information contained in the returns indicates that active price competition has existed on sales to hospitals and it will be noted that special hospital prices are usually quoted on the products most widely used in hospitals. Price competition in sales to retailers has been less evident. It would appear that competition at the hospital level drives prices to hospitals down and that these reductions subsequently affect prices to retailers. Since penicillin is a prescription drug, there is, of course, normally no price competition in sales to the public. The purchaser buys the product specified by the doctor writing the prescription.

268. New types of penicillin include benzathine penicillin G, various types of penicillin V (phenoxymethyl penicillin) and the new synthetic penicillin, phenilethylpenicillin potassium, commonly referred to as penicillin 152. Information furnished to the Director in 1958 indicates that patents on benzathine penicillin G are held by American Home Products Corporation, the American parent of Ayerst and Wyeth which sell dosage forms of this drug in Canada. Frosst also sells dosage forms of this drug. It reported that it did not hold patents, nor was it licensed, but that it manufactured the drug by a non-infringing process.

269. Penicillin V is sold by Lilly and Wyeth. Patents rights are held by Eli Lilly and Company, Indiana, and Wyeth sells under an agreement between Eli Lilly and Company and American Home Products Corporation. Potassium penicillin V is covered by the same patent and agreement. Abbott imports this drug from its U.S. parent company, presumably under agreement. The drug is also sold by a number of firms which obtain supplies from

Denmark or Italy, apparently without licences from the Canadian patent holder.

270. Penicillin 152 was developed quite recently. An official of Beecham reported to the Director:

" . . . Penicillin Compound 152 (Brocsil) was synthesized by Beecham Research Laboratories in the U.K. and has been brought to commercial production through a joint research agreement with Bristol Laboratories U.S.A. . . ."

Dosage forms are sold only by these two firms.

271. Reported costs of the newer penicillins varied widely. Costs of benzathine penicillin G were reported as of the order of \$45.00 per BU which would be equivalent to approximately \$54.00 per kg. Penicillin V was reported to cost \$196.20 per kg. Costs of potassium penicillin V were reported as about \$120.00 per kg. by two firms and as about \$265.00 by a third. Atlantic Trading Company which acts as an agent for Italian and Danish firms and would presumably be supplying firms not buying under arrangements with patent holders, reported that during 1959 it sold potassium penicillin V at prices ranging from \$44.00 to \$73.00 per kg. f.o.b. Europe.

272. Penicillin 152 is much more expensive than the other types mentioned. There were some differences in the costs reported by Bristol and Beecham. It would appear costs may be as high as \$450.00 per kg.

273. Costs of prepared dosage forms of these drugs also varied widely. as would be expected. Examples of costs reported for a package of 100 tablets or capsules of 200,000 I.U. or 125 mg. were, for benzathine penicillin G, \$1.54; for penicillin V, \$3.17; for potassium penicillin V, \$2.68; and for penicillin 152, \$4.65 to \$6.48 plus packaging.

274. Despite varying costs, most firms sell dosage forms of these penicillins at substantially identical prices. This is illustrated by the comparative prices of tablets and capsules set out below. Brand names are shown and are used by the respective firms for the following drugs:

Benzathine penicillin G

Ayerst - Duapen
Wyeth - Bicillin

Penicillin V

Lilly - V-Cillin
Wyeth - Pen Vee

Potassium penicillin V

Abbott - Compocillin VK
 Frosst - PVF
 Lilly - V-Cillin K
 Mowatt & Moore - Penevin
 Wyeth - Pen Vee K

Penicillin 152

Beecham - Brocsil
 Bristol - Syncillin.

TABLETS AND CAPSULES

125 mg., 200,000 I.U.

		<u>Size</u>	<u>List</u> \$	<u>Retailer</u> \$	<u>Hospital</u> \$
Lilly	V-Cillin K	10's	3.75	2.25 ^x	2.25 STI
Ayerst	Duapen	12's	4.50	2.70	2.34
Beecham	Brocsil	"	4.50	2.70 ^x	
Bristol	Syncillin	"	4.50	2.70 ^x	2.70 STI
Frosst	PVF	"	4.50	2.70 ^x	2.70 STI
Lilly	V-Cillin	"	4.50	2.70 ^x	2.70 STI
Mowatt & Moore (14 tablets of 133 mg. each)	Penevin	14's	4.50	2.70 ^x	2.70 STI
Wyeth	Bicillin	12's	4.50	2.70	2.34
	Pen Vee Oral	"	4.50	2.70	2.34
	Pen Vee K	"	4.50	2.70	2.34

(Prices for a similar package of penicillin G potassium tablets vary. Glaxo-Allenbury lists Crystapen at \$1.40 while Squibb lists Pentids at \$2.45.)

Abbott	Compocillin VK	50's	17.15	10.29	9.27
Lilly	V-Cillin	"	17.00	10.20 ^x	10.20 STI
	V-Cillin K	"	17.00	10.20 ^x	10.20 STI
Ayerst	Duapen	100's	33.75	20.25	18.41
Beecham	Brocsil	"	33.80	20.28 ^x	
Bristol	Syncillin	"	33.80	20.28 ^x	20.28 STI
Wyeth	Bicillin	"	33.75	20.25	18.41
	Pen Vee Oral	"	33.75	20.25	18.41
	Pen Vee K	"	33.75	20.25	18.41

(List price for the 100 tablet package of Crystapen is \$9.56 and for Pentids is \$18.60.)

250 mg., 400,000 I.U.

Lilly	V-Cillin K	10's	6.25	3.75 ^x	3.75 STI
Beecham	Brocsil	12's	7.50	4.50 ^x	
Bristol	Syncillin	"	7.50	4.50 ^x	4.50 STI
Lilly	V-Cillin	"	7.50	4.50 ^x	4.50 STI
Wyeth	Pen Vee L-A	"	7.50	4.50	3.89
	Pen Vee K	"	7.50	4.50	3.89
Abbott	Compocillin VK	25's	15.40	9.24	8.32
Lilly	V-Cillin K	50's	28.00	16.80 ^x	16.80 STI

		<u>Size</u>	<u>List</u> \$	<u>Retailer</u> \$	<u>Hospital</u> \$
Beecham	Brocsil	100's	56.20	33.72*	
Bristol	Syncillin	"	56.20	33.72*	33.72 STI
Wyeth	Pen Vee L-A	"	56.25	33.75	30.68
	Pen Vee K	"	56.25	33.75	30.68

(List prices for 100 tablets of 400,000 I.U. of potassium penicillin G range around \$20.00.)

300 or 312.5 mg., 500,000 I.U.

Frosst	PVF	12's	9.00	5.40*	5.40 STI
Wyeth	Pen Vee Oral	"	9.00	5.40	4.66
Wyeth	Pen Vee Oral	100's	67.50	40.50	36.82

275. Gilbert lists potassium penicillin V tablets at the following prices:

	<u>Size</u>	<u>List</u> \$	<u>Retailer</u> \$	<u>Hospital</u> \$
200,000 I.U.	100's	25.00	10.00	9.00*
500,000 I.U.	100's		20.00	18.00*

276. Most firms allow some discount on quantity purchases and a few show special prices to hospitals on these drugs. Here, as elsewhere, it is sometimes difficult to determine these prices exactly because they are usually not stated directly along with the regular price of the dosage form, but must be calculated from varying rates of discounts applicable to different products, different quantities and different buyers. However, Frosst lists the following special prices on its PVF tablets, the regular prices of which are shown above. (These special prices are substantially below those which can be determined for other firms.)

Prices to hospitals - Frosst Tablet No. 536
PVF (potassium penicillin V), 200,000 I.U.,
package of 12 tablets

<u>Quantity</u>	<u>Price</u> \$	<u>Equivalent Price</u> <u>Per Tablet</u> \$
12 x 12		
6 x 12 free	24.00 for lot	0.11
36 x 12		
12 x 12 free	52.00 for lot	0.09
360 x 12		
144 x 12 free	362.50 for lot	0.06

Similar special prices are allowed on quantity purchases of the 500,000 I.U. tablets (PVF - No. 537) by hospitals and the corresponding prices are 22, 18 and 12 cents per tablet.

277. Frosst also offered special prices to dealers (instruction dated April 2, 1959, and stated to be "Special Temporary Prices"):

PVF, 200,000 I.U., packages of 12 tablets

<u>Quantity</u>	<u>Price per Package</u> \$
12 packages	2.00
36 "	1.90
72 "	1.80
144 "	1.70

PVF, 500,000 I.U., packages of 12 tablets

12 packages	4.00
36 "	3.80
72 "	3.60
144 "	3.40

278. These points may be noted about the prices of the newer penicillins:

- (a) Costs of the basic drugs and of prepared dosage forms vary widely.
- (b) Despite this, list prices, and prices to the trade where no special discount is involved, are substantially identical for products sold by the large firms.
- (c) These list prices are much higher than those for equivalent forms of older penicillin.
- (d) Special low prices to hospitals are much less common than in the case of older penicillins although, as noted, there are some exceptions as in the case of Frosst.
- (e) As in the case of the older penicillins, any such special prices increase the spread between prices to hospitals and prices to persons purchasing on prescription. Thus, on the basis of Frosst's prices shown, while a hospital purchasing in quantity would pay 72 cents for twelve 200,000 I.U. tablets of potassium penicillin V, a person purchasing in a drug store would normally pay \$4.50 plus any prescription fee added (under the Ontario suggested schedule, the price would be \$5.35).

Streptomycin and Dihydrostreptomycin

279. The price history of these drugs is parallel to that of the older penicillins. These drugs were the next antibiotics to be discovered after penicillin and were extremely high priced at first. Figures cited in the FTC Report indicate that the price of bulk streptomycin fell from \$16.00 per gram in 1946 to \$0.075 per gram in 1956. Since about 1948, the prices of both drugs have been approximately the same.

280. Both drugs are widely used in combination with other drugs and with each other. One of the dosage forms of each drug by itself is the one gram vial. Manufacturers reported costs of this dosage form (both purchased and manufactured) as ranging from 21 cents to 30 cents. Parke-Davis's selling prices may be taken as typical and for the one gram vial of dihydrostreptomycin were reported as:

<u>List</u>	<u>Retailer</u>	<u>Hospital</u>
\$	\$	\$
.77	.46	.41

Price changes reported by Parke-Davis also indicate the trend of prices of these drugs. For the same dosage form, previous list prices were:

January 8, 1948 .	\$2.90
March 7, 1949 ...	1.63
December 23, 1949	1.35
June 1, 1951	1.37
March 4, 1952 ...	1.27
March 25, 1952 ..	.82
June 18, 195477

281. Prices quoted to Departments of the Federal Government have been as follows:

Ayerst	\$0.36
Gilbert	0.135
Lilly	0.31
Merck	0.17
Pfizer	0.23 - 0.1475
Parke-Davis	0.36
Squibb	0.37 - 0.35

282. In summary, streptomycin and dihydrostreptomycin are now low-cost drugs. They are freely available from a number of suppliers. The drugs are not subject to patent control.

Broad-Spectrum Antibiotics

283. There are five broad-spectrum antibiotic drugs - so called because of the wide range of their effectiveness - chloramphenicol, chlortetracycline, oxytetracycline, tetracycline and demethylchlortetracycline.

284. Chloramphenicol is manufactured in Canada by Parke-Davis and by Fine Chemicals under a compulsory licence under Parke-Davis's patents. Reported cost of manufacture is of the order of \$90.00 per kg. Fine Chemicals' selling price to other manufacturers is \$200.00 per kg. plus royalty. (The amount of the royalty to be paid Parke-Davis under the compulsory licence had not been determined at the time information was submitted to the Director.) Chloramphenicol is imported from Europe by several firms which presumably

cannot obtain the drug from Canadian suppliers. Atlantic Trading Company reported that prices during 1959 ranged from \$60.00 to \$250.00 per kg. depending on the size of the order and whether the drug was brought in by air or by ship. These prices were stated to be C.I.F. Montreal or Toronto, but did not include duty.

285. Chlortetracycline is sold only by Cyanamid under the trade name Aureomycin. The basic drug is purchased from American Cyanamid Company at \$340.02 per kg. and refined in Canada. The total cost of refined chlortetracycline is \$476.51 per kg. Manufacture of chlortetracycline (rather than simply refining the crude drug) was begun by Cyanamid in Canada in November 1959, but the operations were still in the "break-in" period at the time information was supplied to the Director.

286. Oxytetracycline is sold in Canada by Pfizer under the trade name Terramycin. Pfizer imports the drug from Chas. Pfizer & Co., Inc., which is the holder of the Canadian patents, at a reported cost ranging from \$63.37 to \$281.13 per kg. The drug is also imported and sold by Gilbert which imports prepared dosage forms only.

287. Tetracycline is sold by several firms. Apparently, patents in relation to the drug follow the arrangements in the United States where the basic patents are held by Pfizer. Cyanamid and Bristol are licensed to manufacture and sell the drug, and Squibb and Upjohn are licensed to purchase and sell the drug. Tetracycline is also imported and sold by Gilbert.

288. Reported costs of tetracycline vary widely. Bristol imports from its U.S. parent at a cost of slightly over \$140.00 per kg. (up from \$90.00 in 1958). Bristol sells to Squibb and Upjohn. Bristol reported different prices than Squibb and Upjohn, but these differences were apparently due to allowances of extra quantities and with factors having to do with stability and moisture content of different forms of the drug. Squibb reported it paid prices ranging from \$262.94 per kg. for tetracycline phosphate complex to \$386.57 for tetracycline base. Upjohn reported it paid \$372.24 for tetracycline hydrochloride and \$414.50 for tetracycline base. Cyanamid reported it manufactured tetracycline in Canada at a cost of \$644.15 per kg. Pfizer imports tetracycline from Chas. Pfizer & Co., Inc. at prices varying from \$156.71 to \$525.36. Gilbert formerly imported only

dosage forms, but now imports the basic drug at a cost of \$300.00 per kg.

289. Demethylchlortetracycline is sold in Canada by Cyanamid under the trade name Declomycin. It was first marketed in October 1959. The drug is purchased in the crude form from American Cyanamid Company at \$340.05 per kg. and refined in Canada. Total cost of the refined drug was reported by Cyanamid as \$606.47 per kg.

290. It will thus be seen that costs of chlortetracycline are available from one source only, that costs of oxytetracycline are also available from one source only, but that costs of tetracycline are available from several sources and two of the companies dealing in this drug deal in chlortetracycline and oxytetracycline respectively. Similarly, demethylchlortetracycline is marketed only by Cyanamid, but this company is one of those marketing tetracycline.

291. Cost figures supplied by the several firms marketing tetracycline vary by as much as several hundred dollars per kg. However, taking the comparative figures for the several drugs, Cyanamid reports that chlortetracycline is the cheapest, demethylchlortetracycline is the next most costly, and tetracycline the most expensive. Also, in an earlier return which gave the costs of various dosage forms, the cost of preparing dosage forms of chlortetracycline was shown as being lower than the cost of preparing equivalent dosage forms of tetracycline. (Demethylchlortetracycline was not on the market at that time.) The information submitted by Pfizer is to the same effect. Instead of giving a cost price it gave a range of cost prices, but the range for oxytetracycline is well below that for tetracycline. In supplying information on costs of dosage forms, it gave costs as a percentage of net sales, and those for dosage forms of oxytetracycline appear to average a few percentage points below those for tetracycline. As selling prices were the same, this also tends to show that the cost of oxytetracycline was less than that of tetracycline.

292. The available information thus indicates that the costs of manufacturing chlortetracycline and oxytetracycline are below the cost of manufacturing tetracycline. Now, if it is assumed that the cost reported by Bristol represents the cost at which tetracycline can be manufactured, then the other reported costs are very high, not only for tetracycline but for

chlortetracycline and oxytetracycline as well. This is not to suggest that reported costs are not actual costs of those companies reporting such costs. However, as will be illustrated below, the selling prices of equivalent dosage forms of all the broad-spectrum antibiotic drugs sold by the large drug firms are substantially the same. Unless some of these firms are selling dosage forms of certain drugs at a loss, this would appear to indicate that selling prices are high enough to allow the highest-priced drugs to be sold at a profit. If this is correct, the prices at which the lower-priced drugs are sold are proportionately higher in relation to cost.

293. Reported costs of dosage forms are not too clear. As already noted, Pfizer reported costs as a percentage of net sales rather than as a precise figure. Parke-Davis reported total costs of its antibiotic division rather than costs of individual products. Of the costs reported by the large firms, those of a typical dosage form, 100 capsules of 250 mg. each, ranged from \$3.02 to \$17.61. This dosage form is imported by Gilbert at reported costs of \$24.00 per 1,000 (\$2.40 per 100) for chloramphenicol; \$168.00 per 1,000 (\$16.80 per 100) for oxytetracycline; and \$90.00 per 1,000 (\$9.00 per 100) for tetracycline. Presumably, these prices would be f.o.b. Italy or Denmark and would not include duty. Empire reported purchasing chloramphenicol, 250 mg. capsules, at a cost of \$23.50 (U.S. funds) per 1,000 f.o.b. Denmark. This would not include duty. Atlantic Trading Company reported that during 1959 its prices to drug manufacturers for this dosage form were \$140.00 per 1,000 (\$14.00 per 100) for oxytetracycline; \$28.00-\$20.00 per 1,000 (\$2.80-\$2.00 per 100) for chloramphenicol, and \$110.00 per 1,000 (\$11.00 per 100) for tetracycline. These were f.o.b. prices and did not include duty.

294. The broad-spectrum antibiotics are sold under various trade names as follows:

<u>Trade Name</u>	<u>Manufacturer</u>	<u>Generic Name</u>
Achrocidin (syrup)	Cyanamid	Tetracycline HCL / six other ingredients
Achrocidin (tablets)	Cyanamid	Tetracycline HCL / four other ingredients
Achromycin	Cyanamid	Tetracycline HCL

<u>Trade Name</u>	<u>Manufacturer</u>	<u>Generic Name</u>
Achromycin V	Cyanamid	Tetracycline HCL / sodium metaphosphate
Achrostatin V	Cyanamid	Tetracycline HCL / sodium metaphosphate / nystatin
Albamycin T	Upjohn	Tetracycline HCL / novobiocin calcium
Aureomycin	Cyanamid	Chlortetracycline
Chloromycetin	Parke-Davis	Chloramphenicol
Cosa-Terramycin	Pfizer	Oxytetracycline / glucosamine
Cosa-Tetracyn	Pfizer	Tetracycline HCL / glucosamine
Cosa-Tetrastatin	Pfizer	Tetracycline HCL / glucosamine / nystatin
Declomycin	Cyanamid	Demethylchlortetracycline
Mysteclin	Squibb	Tetracycline phosphate complex
Mysteclin V	Squibb	Tetracycline phosphate complex / nystatin
Panmycin	Upjohn	Tetracycline HCL
Polycycline	Bristol	Tetracycline HCL
Signemycin	Pfizer	Tetracycline HCL / oleandomycin
Steclin	Squibb	Tetracycline HCL
Terramycin	Pfizer	Oxytetracycline
Tetracyn	Pfizer	Tetracycline HCL
Tetrex	Bristol	Tetracycline phosphate complex

(These are the products reported by the manufacturers at the time information was submitted. Examination of trade journals and other sources indicates that new combinations are being developed. For example, it is understood that Bristol has recently released a new combination under the name Azotrex which contains tetracycline phosphate complex plus sulfamethizole plus phenylazo-diamino-pyridine.)

295. The list prices of the various manufacturers for comparable dosage forms are similar. Most of these prices were previously identical and the slight differences which now exist are due to adjustments made when the sales tax was increased from 10 to 11 per cent. The following table shows comparative list prices: [Note: The prices shown were those in effect until the Fall of 1960. Price reductions in these and some other drugs, of the order of about fifteen per cent, were reportedly made by the larger manufacturers towards the end of 1960, but details are not available.]

	Tablets or Capsules		I.V. or I.M. Injectable		Oral Suspension		Pedia- tric
	250 mg. 16's	100's	250 mg.	500 mg.	2 oz. 16 oz. (60 cc.)		Drops
	↓	↓	↓	↓	↓	↓	↓
Bristol							
Polycycline	9.44	56.60	3.56	6.42			
Tetrex	9.44	56.60	3.58		5.60	40.36	3.22
Cyanamid							
Declomycin (150 mg.)	9.44	56.61			5.60		3.23
Aureomycin	9.44	56.61		6.42		40.36	
Achrostatin V (see below) ..							
Achromycin V	9.44	56.61			5.60	40.36	3.23
Achromycin	9.44	56.61	3.57	6.42	5.60		3.23
Parke-Davis							
Chloromycetin	9.45	56.70			5.55		
Pfizer							
Cosa-tetrastatin (see below)							
Cosa-tetracycyn	9.44	56.61			5.60		3.23
Tetracycyn			3.57	6.42	5.60		
Signemycin	9.44	56.61	3.57	6.42	5.60		3.23
Terramycin			3.57	6.42	5.60		3.23
Cosa-terramycin	9.44	56.61			5.60		3.23
Squibb							
Mysteclin (discontinued) ...							
Mysteclin V (see below)							
Steclin (discontinued).....							
Upjohn							
Panmycin	9.43	56.62					
Albamycin T	9.43	56.62		6.30	5.60		3.23
<hr/>							
Cyanamid - Achrostatin V	10.19	60.55			5.60		
Pfizer - Cosa-tetrastatin	7.62	60.55			5.60		
	(pkg.of 12)						
Squibb - Mysteclin V	10.19	60.55			5.60		3.23

296. Taking the 250 mg. capsules as an example, the list prices shown reflect other trade prices similar to the following:

	<u>Size</u>	<u>List</u>	<u>Retailer</u>	<u>Hospital</u>
		\$	\$	\$
Chloromycetin...	16's	9.45	5.67	5.10
Achromycin	"	9.44	5.66	5.10
Chloromycetin ..	100's	56.70	34.02	30.62
Achromycin	"	56.61	33.97	30.60

297. Other suppliers of these drugs, besides the large manufacturers shown, include Intra, Empire and Gilbert in the case of chloramphenicol, and Gilbert in the case of tetracycline and oxytetracycline. Comparative prices reported by these firms were:

<u>Chloramphenicol</u>	<u>Size</u>	<u>List</u> ↓	<u>Retailer</u> ↓	<u>Hospital</u> ↓
Intra - Enicol .	16's	6.70	4.02 ^x	3.62 ^x
Intra - Enicol ..	100's	39.70	23.82 ^x	21.44 ^x
Gilbert.....	"	40.00	18.00	16.20 ^x
Empire	"		12.75	11.48 ^x

<u>Oxytetracycline</u>				
Gilbert - Oxytet.	100's	56.00	26.00	23.40 ^x

<u>Tetracycline</u>				
Gilbert	100's	52.00	24.00	21.60 ^x

298. Examples of prices quoted to Departments of the Federal Government during 1958 and 1959 are given below. In each case, the price is for 100 capsules of 250 mg.

<u>Chloramphenicol</u>			
Parke-Davis	-	\$20.35	- \$11.25
Gilbert	-	10.75	- 10.45
Bio-Chemical	-	15.00	

<u>Chlortetracycline</u>			
Cyanamid	-	\$24.22	- \$18.55

<u>Oxytetracycline</u>			
Pfizer	-	\$16.50	- \$15.94
Gilbert	-	24.00	- 21.00

<u>Tetracycline</u>			
Bristol	-	\$15.95	- \$14.35
Cyanamid	-	17.01	- 16.50
Gilbert	-	26.00	- 13.75
Pfizer	-	16.44	- 15.94
Squibb	-	16.24	- 14.89

299. The price history of the broad spectrum drugs is of interest. If the package of 16 capsules of 250 mg. per capsule is taken as an example, the price history in the United States is as follows: Aureomycin (chlortetracycline) was introduced by Cyanamid on December 1, 1948, at a trade price (60 per cent of list price) of \$15.00. About February 1, 1949, the price was reduced to \$10.00. On March 25, 1949, Parke-Davis introduced Chloromycetin (chloramphenicol) at the same price. On February 1, 1950, both Cyanamid and Parke-Davis reduced their prices to \$8.00. On April 1, 1950, Pfizer introduced Terramycin (oxytetracycline) at \$8.40. On May 1, 1950, Cyanamid and Parke-Davis reduced the prices of Aureomycin and Chloromycetin to \$6.00. Pfizer reduced Terramycin to \$6.00 on November 1, 1950. On

September 27, 1951, Pfizer reduced Terramycin to \$5.10 and the same price was adopted by Cyanamid on Aureomycin and by Parke-Davis on Chloramphenicol on October 1, 1951. In 1953, tetracycline was introduced and was eventually marketed by five firms, Bristol, Cyanamid, Pfizer, Squibb and Upjohn. It was introduced at the same price as the other broad spectrum antibiotics and prices of all of these drugs have remained unchanged.

300. The price history of this dosage form in Canada is set out below along with the U.S. prices. For comparative purposes, U.S. trade prices have been converted to list prices by taking the trade price as 60 per cent and then calculating 100 per cent. This may result in an error where a fraction of a cent has to be rounded off but, subject only to this, the figures should be accurate.

(a) Chloromycetin - Parke-Davis.

	<u>Canada</u> \$	<u>U.S.</u> \$
March 25, 1949 .		16.67
February 1, 1950		13.33
May 1, 1950	12.85	10.00
June 1, 1951 ...	13.10	
October 1, 1951.	11.13	8.50
October 6, 1953.	9.35	
April 16, 1959..	9.45*	

*Adjustment to reflect increased sales tax.

(b) Aureomycin -Cyanamid

December 1, 1948		25.00
February 1, 1949		16.67
February 5, 1949	21.40	
February 1, 1950	17.01	13.33
May 1, 1950		10.00
May 2, 1950	12.85	
April 10, 1951..	13.08*	
October 1, 1951.	11.13	8.50
October 5, 1953.	9.35	
April 10, 1959..	9.44*	

*Adjustment to reflect increased sales tax. (Cyanamid supplied trade prices for Canada, these have been converted to list prices.)

(c) Terramycin and Cosa-Terramycin (which replaced Terramycin)
- Pfizer.

April 1, 1950 ...		14.00
November 1, 1950.		10.00
September 27, 1951		8.50
March 1955	9.35	
April 1959	9.44*	

*Adjustment to reflect increased sales tax.
(Information on Canadian prices prior to March 1955 was not available.)

(d) Tetracycline - Tetracycline HCL was introduced in the U.S. in 1953 at a list price of \$8.50. Subsequently, tetracycline phosphate complex was introduced by certain firms and, still later, combinations of tetracycline with other drugs were also introduced. Prices were the same (and, as reported in the 1960 Drug Topics Red Book, are the same) as for the three broad spectrum antibiotic drugs listed above except that certain combination dosage forms are slightly higher priced. Prices have remained unchanged.

301. In Canada, prices remained unchanged from 1953, except for a slight adjustment in 1959 to reflect increased sales tax, until certain reductions reportedly made in late 1960.

302. The information obtained by the Director appears to support the following conclusions about costs and selling prices of broad spectrum antibiotic drugs:

(a) The costs reported vary widely, both for different drugs and for the same drug purchased or manufactured by different firms.

(b) In some cases, higher costs of a particular firm are due to the fact that the firm is not licensed to manufacture the drug, but must purchase it from another manufacturer which is licensed to manufacture as, for example, Squibb and Upjohn purchase from Bristol. In other cases, no reason appears for large differences in the cost of the same drug to different firms.

(c) Costs of dosage forms also vary widely.

(d) Despite variations in cost, selling prices of dosage forms are substantially uniform for all the large firms.

(e) Prices of these large firms for dosage forms have remained unchanged in the United States since 1951 and in Canada, subject only to adjustments for changes in the rate of sales tax, since 1953.

(f) Special low prices to hospitals are not normally granted on these products.

(g) On quotations to departments of the Federal Government, the large firms have quoted prices roughly one half their prices to hospitals.

(h) Alternative sources of supply of these drugs, apart from the large manufacturers, are few and these alternative suppliers usually

offer only a limited variety of dosage forms. The differences in the prices quoted by these alternative suppliers have been illustrated above.

(1) Because of the uniformly high list prices, the differential on small purchases by prescription is significant. Thus, while a Government Department can buy Parke-Davis's chloramphenicol at \$0.1125 per capsule, a hospital would pay \$0.3062 and an individual (purchasing 16 capsules) would pay 0.59 per capsule. The latter price would reflect about \$0.06 sales tax, so that \$0.53 is probably more accurate for purposes of comparison.

Erythromycin

303, Erythromycin is sold in Canada by Abbott under the trade name Erythrocin, by Lilly under the trade names Ilotycin and Ilosone (Lilly sells several chemical forms of the drug), and by Upjohn under the generic name erythromycin. Both Lilly and Upjohn import the drug in prepared dosage forms from their respective parent companies. Abbott imports some dosage forms but also imports the basic drug and reported the following costs:

Erythromycin stearate base .	\$160.00 kg.
" lactobionate ..	310.00 "
" sulphate	730.00 "
" ethyl succinate	240.00 "

304. One dosage form common to all three firms is 250 mg. tablets (of erythromycin stearate). Two firms reported finished package costs for the small-sized package (24 or 25 tablets) as \$1.25-\$1.28 and of the 100 tablet package as \$4.96-\$5.02. The cost reported by the third firm was considerably higher, this firm imported prepared dosage forms from its parent. Selling prices were reported as:

		<u>Size</u>	<u>List</u>	<u>Retailer</u>	<u>Hospital</u>
			\$	\$	\$
Abbott	Erythrocin stearate	25's	14.75	8.85	7.72
Lilly	Ilotycin	24's	14.00	8.40*	7.56*
Upjohn	Erythromycin	25's	14.72	8.83*	7.94*
Abbott	Erythrocin stearate	100's	56.60	33.96	29.68
Lilly	Ilotycin	100's	56.10	33.60*	30.24*
Upjohn	Erythromycin	100's	56.62	33.97*	30.57*

305. Information as to the price history of this drug was supplied by Abbott, Lilly and Upjohn. List prices are shown:

	<u>A b b o t t</u> Package of 25 \$	<u>L i l l y</u> Package of 24 \$	<u>U p j o h n</u> Package of 25 \$
October 22, 1953 .		18.25*	
August 23, 1954 ..		16.80	
November 15, 1954.		14.00	
August 1955	14.60		
May 1, 1956			14.58
May 1959	14.75		14.72

(Lilly changed its dosage form from a 200 mg. tablet to a 250 mg. tablet on October 4, 1955.)

306. Prices quoted to Departments of the Federal Government have been as follows (per 100, 250 mg. tablets):

Abbott	\$12.40-\$10.50
Lilly	\$12.35-\$10.18

Other Antibiotics

307. The penicillins, the streptomycins, the broad spectrum antibiotics and erythromycin appear to be the most important antibiotic drugs. The following are brief notes on some of the other antibiotic drugs.

308. Amphotericin B - This drug appears to be sold only by Squibb, in a combination with other drugs, as "Fungizone for Infusion".

309. Bacitracin - This drug appears to be most widely used in combinations with other drugs and especially in ointments, although Pfizer and Upjohn, at least, sell vials of the drug for preparing solutions for injection or topical use. Costs of the drug vary, but \$12.00 to \$16.00 per MU would be typical. On this basis, the theoretical cost of the drug in a 50,000 I.U. dosage form would be 60 to 80 cents. Upjohn imports a 50,000 I.U. vial from its parent at \$2.38. Selling prices of the 50,000 I.U. vial were reported as:

	<u>List</u> \$	<u>Retailer</u> \$	<u>Hospital</u> \$
Pfizer	7.87	4.72*	4.25
Upjohn	8.02	4.81*	4.33*

310. Carbomycin - This drug is sold by Desbergers under the name D-Mycin. While the firm previously reported selling tablets, only a chocolate powder preparation is listed in the last price list furnished. Desbergers buys the drug from Pfizer (U.S.). Pfizer sells tablets in the U.S. under the trade name Magnamycin, but did not report selling dosage forms in Canada.

311. Cycloserine - This drug is sold by Lilly under the trade name Seromycin and by Hoffmann-La Roche under the name d-Cycloserine. Lilly

imports prepared dosage forms from its parent, while Hoffmann-La Roche imports prepared dosage forms from its related company in Switzerland. Lilly reported costs of \$5.96 for the 40 capsule package and \$71.93 for the 500 capsule package. Hoffmann-La Roche reported costs of \$6.25 for 40 tablets and \$14.76 for 100 tablets. Selling prices were reported as:

	<u>Size</u>	<u>List</u> \$	<u>Retailer</u> \$	<u>Hospital</u> \$
Hoffmann-La Roche	40's	20.40	11.70	8.86
Lilly	40's	19.50	11.70*	10.53*
Hoffmann-La Roche	100's	49.10	28.20	21.36
(on quantities of 1,000's	414.00 per M.			180.00 per M.)
Lilly	500's	233.34	140.00*	126.00*

312. Fumagillin - This drug is sold in the United States by Abbott under the trade name Fumidil, but is not listed in Abbott's Canadian catalogue.

313. Gramicidin - This drug appears to be used exclusively in combinations with other drugs, particularly in ointments and lotions. The drug is very expensive; costs reported were of the order of \$5.00 to \$6.50 per gram (i.e., \$5,000.00 to \$6,500.00 per kg.).

314. Griseofulvin - This is one of the newer antibiotics. It is sold in dosage form by Ayerst under its generic name, by Glaxo-Allenbury under the trade name Grisovin, by Schering under the trade name Fulvicin and by Vanzant under the trade name Grifulvin. All importers, except Schering, reported that they obtained the drug from England. Prices paid ranged from \$96.00 to \$160.00 per kg., except in the case of Schering. Schering reported a cost of \$220.00 per kg. (which may indicate that Schering's U.S. parent imports the drug from England and exports it to its Canadian subsidiary).

315. No costs of prepared dosage forms are available, but the theoretical cost of the basic drug in 100, 250 mg. tablets would range from \$2.40 to \$4.00 on the basis of costs of \$96.00 to \$160.00 per kg. for the basic drug.

316. Selling prices of 250 mg. tablets were reported as:

	<u>Size</u>	<u>List</u> \$	<u>Retailer</u> \$	<u>Hospital</u> \$
Vanzant	16's	4.00	2.40 ^d	2.16
Glaxo-Allenbury.	25's	6.25	3.75*	3.38*
Schering	30's	7.50	4.50*	4.05*
Ayerst	50's	12.00	7.20	6.48

(Cont'd)

	<u>Size</u>	<u>List</u> \$	<u>Retailer</u> \$	<u>Hospital</u> \$
Glaxo-Allenbury	100's	24.00	14.40 ^x	12.96 ^x
Schering	100's	24.00	14.40 ^x	12.96
Vanzant	100's	24.00	14.40 ^x ✓	12.96
Ayerst	500's	115.00	69.00	62.10
Schering	500's	115.00	69.00 ^x	62.10
Vanzant	500's	115.00	69.00 ^x ✓	62.10

✓For a period at least, retailers were allowed an additional 10 per cent discount off prices shown.

317. Kanamycin - Dosage forms of this drug are sold by Bristol under the trade name Kantrex. It is supplied in capsules of 0.5 grams for oral administration and in injectable forms - 0.5 grams, 2 c.c., and 1 gram, 3 c.c. Bristol purchases the basic drug from its U.S. parent at \$207.90 per kg., or approximately 21 cents per gram. Reported selling prices are:

	<u>Size</u>	<u>List</u> \$	<u>Retailer</u> \$	<u>Hospital</u> \$
Capsules, 0.5 grams	20's	17.66	10.69 ^x	9.62 ^x
	100's	84.76	50.86	45.77
Injections				
0.5 grams, 2 c.c.	vial	4.44	2.66 ^x	2.39 ^x
1 gram, 3 c.c.	"	7.56	4.54 ^x	4.08 ^x

318. Neomycin - This drug appears to be most widely used in combination with other drugs, although Upjohn sells a number of dosage forms of the drug itself under the trade name Mycifradin. Upjohn imports the drug from the U.S. at \$264.00 per kg. and from England at \$220.00 per kg. Pfizer sells the drug to other drug manufacturers at \$340.00 per kg. The theoretical cost of the drug in Upjohn Mycifradin 0.5 gram tablets (at a cost for the basic drug of \$264.00) would be \$2.64 for 20 tablets and \$13.20 for 100 tablets. List prices are \$17.67 and \$84.77 respectively. Prices to retailers would be \$10.60 and \$50.86 and to hospitals \$9.54 and \$45.77 (all calculated). Upjohn has quoted Departments of the Federal Government prices ranging from \$8.48 to \$7.95 per bottle of 20.

319. Another dosage form is neomycin sulphate powder in 0.5 gram vials. Upjohn's prices are list \$4.38, retailer \$2.63 and hospital \$2.37 (retailer and hospital prices calculated). Prices quoted on tenders to the Federal Government have been \$2.10 to \$1.80.

320. Novobiocin - Dosage forms of this drug are sold by Merck under the trade name Cathomycin and by Upjohn under the trade name Albamycin. Merck imports the drug from its parent at \$276.50 per kg. (for both novobiocin sodium and novobiocin calcium). Upjohn imports novobiocin calcium from England at \$378.00 per kg. and from the U.S. at \$434.70 per kg. (which equals the English price plus duty at 15 per cent). It imports novobiocin sodium in prepared dosage forms of 250 mg. capsules at \$146.40 per 1,000 (or \$14.64 per 100).

321. Selling prices of both firms for the 250 mg. capsule dosage are similar. (Merck's prices are taken from the Canadian Pharmaceutical Journal Price Book.)

		<u>Size</u>	<u>List</u> \$	<u>Retailer</u> \$	<u>Hospital</u> \$
Merck	Cathomycin	16's	11.62	6.97*	6.27
Upjohn	Albamycin	16's	11.60	6.96*	6.26*
Merck	Cathomycin	100's	71.20	42.72*	38.45
Upjohn	Albamycin	100's	71.13	42.67*	38.40*

As noted, Upjohn's cost for this dosage form is \$14.64 per 100. The theoretical cost of the drug in 100, 250 mg. capsules at Merck's buying price of \$276.50 would be \$6.91.

322. Nystatin - This drug is sold in combination with other drugs by several firms, but apparently only by Squibb as a single drug. Squibb sells it under the trade name Mycostatin. Squibb buys nystatin in bulk from its U.S. parent at about \$110.00 per kg. Taking 1.58 billion units as equal to one pound (the ratio given in the FTC Report), this works out to about \$31.60 per BU. On this basis, the theoretical cost of the drug in 500,000 I.U. tablets would be 19 cents for 12 tablets and \$1.58 for 100 tablets. Costs of prepared and packaged dosage forms were reported by Squibb in 1958 as 40 cents and \$2.44 respectively (at that date the cost of the basic drug was slightly higher).

323. Squibb's selling prices for the 500,000 I.U. tablets were reported to be:

		<u>Size</u>	<u>List</u> \$	<u>Retailer</u> \$	<u>Hospital</u> \$
Mycostatin Oral Tablets		12's	1.95	1.17	1.05
"	"	100's	14.60	8.76	7.89

Squibb's prices to Departments of the Federal Government ranged from \$7.23

to \$7.89 per 100 tablets. Squibb was the only firm quoting on this product and, as noted, quoted either its regular hospital price or a few cents below that price.

324. Oleandomycin - This drug is imported from its U.S. parent by Pfizer at prices ranging from about \$230.00 to \$270.00 per kg. Hoffmann-La Roche reported that it purchased prepared capsules from Pfizer at the following prices:

100 mg. capsules	12's	\$0.90
	100's	6.48
250 mg. capsules	16's	2.60
	100's	15.36

These are resold under the trade name Romicil. Pfizer sells dosage forms of triacetyloleandomycin (which, according to New and Nonofficial Drugs, 1960, has the same actions and uses as oleandomycin) under the trade name Olicin. Selling prices were reported as:

	<u>Size</u>	<u>List</u> \$	<u>Retailer</u> \$	<u>Hospital</u> \$
100 mg. Romicil	12's	3.20	1.92*	1.44
	100's	25.50	15.30*	11.49
250 mg. Olicin	12's	7.08	4.25*	3.83
Romicil	16's	9.45	5.67*	4.25
Olicin	100's	56.61	33.97*	30.60
Romicil	100's	56.60	33.96*	25.50

325. Polymyxin B - There are apparently no dosage forms of this drug as such, although there are of polymyxin B sulphate. However, both seem to be most widely used in combination with various other drugs.

326. Ristocetin - This is one of the newer antibiotic drugs. It is sold by Abbott under the trade name Spontin in one dosage form only - vials of 500 mg. Abbott purchases the finished dosage form from its parent at \$3.22 per vial. Selling prices are:

<u>List</u> \$	<u>Retailer</u> \$	<u>Hospital</u> \$
7.35	4.41	3.95

327. Spiramycine - Dosage forms of this drug are sold by Poulenc under the trade name Rovamycine. The drug is purchased in England at a cost of \$158.64 per kg. On this basis, the theoretical cost of the drug in 100 capsules of 250 mg. would be \$3.97. Selling prices for capsules were reported as:

	<u>Size</u>	<u>List</u>	<u>Retailer</u>	<u>Hospital</u>
		\$	\$	\$
250 mg.	16's	5.20	3.12	2.60
	100's	29.50	17.70	14.75
	250's	67.00	40.20	33.50
Purchases of 25,000 -				
per 250		63.50	38.10	31.75
500 mg.	16's	9.00	5.40	4.50
	100's	51.00	30.60	25.50
	250's	116.00	69.60	58.00
Purchases of 25,000 -				
per 250		110.00	66.00	55.00

328. Thiostrepton - The only reference to this drug is by Squibb which reports it among the antibiotics which it purchases. The only dosage form listed by Squibb containing the drug is Neothion, a veterinary product containing thiostrepton and neomycin.

329. Tyrothricin - This drug, when not used in combinations, is applied locally and not administered orally or by injection. The only dosage forms of the drug itself which are sold are apparently topical solutions of various strengths. The drug is widely used in combination with other drugs in ointments, lotions, lozenges, etc.; the American Drug Index lists 68 combination dosage-form products (some of which would be similar products by different manufacturers).

330. Vancomycin - A dosage form of this drug is sold by Lilly under the trade name Vancocin. It is sold as an injectable solution in 10 c.c. ampoules which contain 500 mg. of the drug. The ampoules are purchased by Lilly from its parent for \$2.88 each. The list price is \$10.60, the price to the retailer \$6.36 (calculated) and the price to hospitals \$5.72 (calculated).

331. Viomycin - Dosage forms of this drug are sold by Ciba under the trade name Vinactane, by Pfizer under the trade name Viocin and by Parke-Davis under its generic name. The basic drug is imported by Pfizer from Pfizer Corporation at a cost of \$384.93 per kg. (approximately 38.5 cents per gram). Pfizer sells prepared dosage forms to Parke-Davis. It also sold prepared dosage forms to Ciba, but Ciba now obtains its requirements from Ciba Laboratories Limited, England. Costs of the prepared dosage forms to Parke-Davis and Ciba are \$1.00 for the one gram size and \$4.74-\$4.75 for the five gram size. Selling prices were reported as:

		<u>List</u> \$	<u>Retailer</u> \$	<u>Hospital</u> \$
Ciba	1 gram	3.95	2.37*	2.37 STI
Parke-Davis	" "	3.90	2.34	2.11
Pfizer	" "	3.94	2.36*	2.13
Ciba	5 grams	16.70	10.02*	10.02 STI
Parke-Davis	" "	16.55	9.93	8.94
Pfizer	" "	16.70	10.02*	9.02

Ataraxic or Tranquilizer Drugs

332. Benactyzine HCL - Dosage forms of this drug are sold by Horner under the trade names Levil and Levil L/A, and by Canada Pharmacal under the trade name Benetrunk. Bell-Craig sells a product containing the drug under the trade name Alubarb, but this product contains several other ingredients.

333. Bell-Craig obtains the drug from Italy at a cost of \$24.00 per kg., duty and transportation paid. Horner and Canada Pharmacal obtain the drug from Delmar Chemicals; Horner reported its last cost as \$80.00 delivered and Canada Pharmacal reported its cost as \$42.50 per kg. delivered. Delmar Chemicals reported that it only manufactures small quantities and more as a convenience to customers who want it than for commercial reasons.

334. On the basis of a cost of \$42.50 per kg., the theoretical cost of the basic drug in 100 tablets or capsules of three mg. would be slightly over one cent. On the basis of \$80.00 per kg., the theoretical cost would be about two and one half cents.

335. Selling prices of prepared dosage forms were reported to be as follows:

Tablets - 2 mg.

		<u>Size</u>	<u>List</u> \$	<u>Dealer</u> \$	<u>Hospital</u> \$
Horner.....	Levil	100's	3.15	1.89	1.70
(A quantity price to hospitals of \$1.12 was reported.)					

Tablets and Capsules, 3 mg.

Can. Pharmacal	Benetrunk	50's	1.75		
Horner	Levil L/A	100's	4.75	2.85	2.57
(A quantity hospital price of \$1.70 was reported.)					
Can. Pharmacal	Benetrunk	500's	16.00		
Can. Pharmacal	Benetrunk	1,000's	31.00		

336. Horner reported a change in discounts allowed to the trade but, apart from an adjustment to reflect increased sales tax, the list price appears to have remained unchanged. Canada Pharmacal did not report any price changes.

337. Captodiamine HCL - Dosage forms of this drug are sold by Ayerst under the trade name Suvren. Ayerst obtains the drug in Denmark at a laid-down cost of \$52.32 per kg. This price (as of December 31, 1959) is considerably higher than the price the company paid in early 1958. On the basis of this price, the theoretical cost of the basic drug in 100 tablets would be \$0.262 for 50 mg. tablets and \$0.523 for 100 mg. tablets. Selling prices of prepared dosage forms were reported to be as follows:

Tablets - 50 mg.

		<u>Size</u>	<u>List</u> \$	<u>Dealer</u> \$	<u>Hospital</u> \$
Ayerst	Suvren	100's	6.75	4.05	3.65
		1,000's	61.00	36.60	32.94
(A quantity price to hospitals of \$25.25 was reported.)					

Tablets - 100 mg.

Ayerst	Suvren	100's	12.00	7.20	6.48
(A quantity price to hospitals of \$4.96 was reported.)					
Ayerst	Suvren	500's	57.00	34.20	30.78
(A quantity price to hospitals of \$23.60 was reported.)					

338. Chlormezanone - Dosage forms of this drug are sold by Winthrop under the trade name Trancopal. Winthrop imports the drug from its U.S. parent company in bulk quantities of tablets which are simply packaged for resale in Canada. The cost of the tablets and the cost of packaging them was reported as follows:

100 mg. tablets	-	100's	\$0.5142
		1,000's	4.1233
200 mg. tablets	-	100's	0.6543
		1,000's	5.4628.

Selling prices were reported to be as follows:

Trancopal Tablets - Winthrop

	<u>Size</u>	<u>List</u> \$	<u>Retailer</u> \$	<u>Hospital</u> \$	<u>Hospital</u> <u>(Quantity)</u> \$
100 mg.	100's	12.50	7.50	6.756	
	1,000's	117.50	70.50	63.508	57.162
200 mg.	100's	14.50	8.70	7.837	
	1,000's	135.00	81.00	72.972	65.675

Trancopal was first marketed in 1959 and no price changes were reported.

339. Chlorpromazine - Dosage forms of this drug are sold by Poulenc under the trade name Largactil. The same drug is sold in the United States by Smith Kline & French as Thorazine.

340. Poulenc purchases the drug as chlorpromazine hydrochloride (for tablets and drops) from Fine Chemicals at \$53.00 per kg., as chlorpromazine chlorhydrate (for injectable solutions and ampoules) from its parent at \$102.27 per kg., and as chlorpromazine base (for suppositories) from its parent at \$127.30 per kg. Comparative prices paid by Poulenc in 1958 were \$115.00 for chlorpromazine HCL and \$176.00 for chlorpromazine base.

341. Poulenc's selling prices provide for lower prices if a large quantity is purchased. The selling prices drop progressively as the quantity increases. In the prices set out below, the lowest prices on purchases in the maximum quantity brackets only are shown, prices on intermediate quantities have been omitted. Poulenc follows the policy of selling at a special low price to Government Departments and psychiatric hospitals, regardless of the quantity purchased. In a letter explaining this practice, Poulenc remarked that orders from such customers are usually large. It will be noted that this special price is the same as the price to an ordinary public hospital which qualifies for the lowest quantity price. The price to Government Departments and psychiatric hospitals is shown under the heading "Special" in the following table of prices as reported:

Largactil Tablets - Poulenc

	<u>Size</u>	<u>List</u>	<u>Dealer</u>	<u>Hospital</u>	<u>Special</u>
			\$	\$	\$
10 mg.	20's	1.80	1.08	.90	
	100's	8.00	4.80	4.00	
	500's	35.00	21.00	17.50	
	1,000's	60.00	36.00	30.00	21.00
Purchases of 250,000					
per 1,000				21.00	
25 mg.	20's	2.50	1.50	1.25	
	100's	10.50	6.30	5.25	
	500's	45.00	27.00	22.50	
	1,000's	80.00	48.00	40.00	21.00
Purchases of 4,000,000					
per 1,000				21.00	
50 mg.	20's	3.50	2.10	1.75	
	100's	15.00	9.00	7.50	
	500's	65.00	39.00	32.50	
	1,000's	120.00	72.00	60.00	43.00
Purchases of 1,000,000					
per 1,000		86.00	51.60	43.00	
100 mg.	20's	6.00	3.60	3.00	
	100's	25.00	15.00	12.50	
	500's	110.00	66.00	55.00	
	1,000's	180.00	108.00	90.00	53.00
Purchases of 700,000					
per 1,000				53.00	
200 mg.	20's	10.20	6.12	5.10	
	100's	42.50	25.50	21.25	
	500's	187.00	112.20	93.50	
	1,000's	306.00	183.60	153.00	90.00
Purchases of 700,000					
per 1,000				90.00	

342. The first dosage forms of Largactil were put on the market in Canada by Poulenc in October 1954. Other dosage forms and sizes were subsequently added. There was a general reduction in prices in January 1956 and also a revision of the prices charged on large quantities. For example, the trade price on 1,000 tablets of 25 mg. was reduced from \$54.00 to \$48.00 (list prices would be reduced from \$90.00 to \$80.00). Also, prior to that date, prices for large quantities were on a sliding scale on purchases up to 250,000 tablets. After that date, still lower prices were allowed on a sliding scale on purchases up to 4,000,000 tablets. Prices have remained unchanged since January 1956.

343. At the cost of \$53.00 per kg. for the drug used in tablets, the theoretical cost of the basic drug in the various sized tablets would be as follows:

10 mg. tablets, 100	-	\$0.053
25 " " "	-	0.133
50 " " "	-	0.265
100 " " "	-	0.53
200 " " "	-	1.06

344. Chlorpromazine is reported to be subject to patents held by Poulenc's parent firm (Société des Usines Chimiques Rhône-Poulenc). However, it is also sold in Canada by Gilbert and Empire. (An action by Poulenc against Gilbert for patent infringement is before the courts). Gilbert reported a cost of \$41.40 per kg. in May 1960, while Empire reported a cost of \$38.00. Presumably, both prices would be f.o.b. Italy and would not include duty.

345. Selling prices of Gilbert and Empire were reported as:

	<u>Size</u>	<u>List</u> \$	<u>Retailer</u> \$	<u>Hospital</u> \$
25 mg. tablets				
Empire	100's		2.20	1.98 ^x
Gilbert	100's		2.50	2.25 ^x
Empire	1,000's		16.80	15.12 ^x
Gilbert	1,000's	45.00	22.00	19.80 ^x
50 mg. tablets				
Empire	100's		3.80	3.42 ^x
Gilbert	100's		4.50	4.05 ^x
Empire	1,000's		30.00	27.00 ^x
Gilbert	1,000's	82.00	38.00	34.20 ^x
100 mg. tablets				
Empire	100's		5.00	4.50 ^x
Gilbert	100's		8.00	7.20 ^x
Empire	1,000's		44.90	40.41 ^x
Gilbert	1,000's	120.00	75.00	67.50 ^x

346. Deserpidine - Dosage forms of this drug are sold by Abbott under the trade name Harmony1. Abbott purchases the drug in bulk from its U.S. parent at a laid-down cost of \$20.90 per gram (this is up from a cost of \$9.57 per gram reported in 1958). On the basis of a price of \$20.90 per kg., the theoretical cost of the deserpidine in 100 tablets of 0.1 mg. size would be slightly over 20 cents, in 100 tablets of 0.25 mg. size would be slightly over 50 cents, and for 500 tablets of 1.0 mg. size would be \$10.45.

347. Selling prices of prepared dosage forms were reported to be as follows:

Harmonyl Tablets - Abbott

	<u>Size</u>	<u>List</u> \$	<u>Retailer</u> \$	<u>Hospital</u> \$
0.1 mg.	100's	2.55	1.53	1.39
	500's	12.10	7.26	6.55
0.25 mg.	100's	4.55	2.73	2.45
	500's	21.20	12.72	11.45
	1,000's	41.10	24.66	22.23
1.0 mg.	50's	8.60	5.16	4.64
	500's	80.60	48.36	43.55

No special quantity prices to hospitals were reported. The drug is also sold in combination with phenobarbital by Abbott under the trade name Harmonyl-N.

348. Except for a slight increase which appears to be an adjustment for increased sales tax, Abbott has not changed the prices of Harmonyl since its introduction in 1957.

349. Ectylurea - Dosage forms of this drug are sold by Ames under the trade name Nostyn. Tablets of the drug are purchased by Miles Laboratories from Strong Cobb Arner in bulk at \$26.164 per 1,000. Miles Laboratories packages the tablets and sells them to Ames at \$1.33 per bottle of 48 tablets and \$13.00 per bottle of 500 tablets. (Miles Laboratories is a wholly-owned subsidiary of Miles Laboratories, Inc., Elkhart, Indiana, U.S.A., and Ames is a wholly-owned subsidiary of Ames Company, Inc., Elkhart, Indiana, U.S.A. Ames Company, Inc. is a subsidiary of Miles Laboratories, Inc.)

350. Selling prices of the prepared dosage forms were reported to be as follows:

Nostyn Tablets - Ames

	<u>Size</u>	<u>List</u> \$	<u>Retailer</u> \$	<u>Hospital</u> \$
300 mg.	48's	7.25	4.35	3.94
	500's	67.00	40.20	36.28

No special quantity price to hospitals was reported. The price history of this product is not known.

351. Ethchlorvynol - Dosage forms of this drug are sold by Abbott under the trade name Placidyl. Abbott purchases the drug already capsuled from its parent U.S. company at a cost of \$5.46 per thousand 100 mg. capsules, \$9.25 per thousand 200 mg. capsules and \$20.35 per thousand 500 mg. capsules.

352. Selling prices of the prepared dosage forms were reported to be as follows:

Placidyl Capsules - Abbott

	<u>Size</u>	<u>List</u> \$	<u>Retailer</u> \$	<u>Hospital</u> \$
100 mg.	100's	3.00	1.80	1.61
200 mg.	100's	4.20	2.52	2.26
500 mg.	100's	6.00	3.60	3.25

No special quantity prices to hospitals were reported. Subject to a slight increase apparently reflecting increased sales tax, prices have remained unchanged.

353. Hydroxyzine - Dosage forms of this drug are sold by Pfizer under the trade name Atarax. The drug is purchased in bulk from Chas. Pfizer & Co., Inc. (New York) at \$429.91 per kg. (the comparative price in 1958 was \$570.36). At a cost for the basic drug of \$429.91 per kg., the theoretical cost of the drug in the 100 tablet package of 10 mg. tablets would be approximately 43 cents. Selling prices of the prepared dosage forms were reported to be as follows:

Atarax Tablets - Pfizer

	<u>Size</u>	<u>List</u> \$	<u>Retailer</u> \$	<u>Hospital</u> \$
10 mg.	24's	1.66	.99*	
	100's	6.16	3.69*	3.33
	500's	27.55	16.53*	14.89
25 mg.	24's	3.73	2.23*	
	100's	13.82	8.29*	7.47
	500's	62.06	37.24*	33.54
50 mg.	24's	4.24	2.54*	2.29
	100's	16.85	10.11*	9.11

No special quantity prices to hospitals were reported. Atarax tablets in the 10 mg. and 25 mg. sizes were introduced by Pfizer in January 1957 at list prices of \$7.50 and \$15.50 respectively for the 100 tablet package of each size. As will be noted, these prices have now been reduced.

354. Levomepromazine - Dosage forms of this drug are sold by Poulenc under the trade name Nozinan. The drug is purchased in bulk from Société Parisienne d'Expansion Chimique (Specia), Paris, France, at a cost of \$320.04 per kg. At a cost price of \$320.04 per kg., the theoretical cost of the drug in 500 tablets of 25 mg. would be approximately \$4.00. Prices of dosage forms were reported to be (see also explanatory note re Poulenc's

pricing policy under chlorpromazine above):

Nozinan Tablets - Poulenc

	<u>Size</u>	<u>List</u> \$	<u>Retailer</u> \$	<u>Hospital</u> \$	<u>Special</u> \$
2 mg.	50's	2.10	1.26	1.05	
	500's	18.90	11.34	9.45	
	1,000's	34.00	20.40	17.00	11.50
Purchases of 250,000					
per 1,000		23.00	13.80	11.50	
5 mg.	50's	3.20	1.92	1.60	
	500's	28.80	17.28	14.40	
	1,000's	51.80	31.08	25.90	18.50
Purchases of 250,000					
per 1,000		37.00	22.20	18.50	
25 mg.	50's	7.10	4.26	3.55	
	500's	63.00	37.80	31.50	
	1,000's	113.40	68.04	56.70	41.50
Purchases of 250,000					
per 1,000		83.00	49.80	41.50	
50 mg.	50's	9.80	5.88	4.90	
	500's	88.00	52.80	44.00	
	1,000's	158.40	95.04	79.20	59.50
Purchases of 250,000					
per 1,000		119.00	71.40	59.50	

Nozinan Ampoules - Poulenc

	<u>Size</u>	<u>List</u> \$	<u>Retailer</u> \$	<u>Hospital</u> \$	<u>Special</u> \$
1 ml. - 25 mg.	10's	10.00	6.00	5.00	
	100's	90.00	54.00	45.00	38.00
(per 100)	500's	85.00	51.00	42.50	
(per 100)	1,000's	82.00	49.20	41.00	
Purchases of 50,000					
per 100		76.00	45.60	38.00	
2 ml. - 5 mg. per 1 ml					
	10's	8.00	4.80	4.00	
	100's	72.00	43.20	36.00	28.50
(per 100)	500's	66.00	39.60	33.00	
(per 100)	1,000's	63.00	37.80	31.50	
Purchases of 50,000					
per 100		57.00	34.20	28.50	

355. Meprobamate - Meprobamate is patented in Canada by Carter Products Inc., New York, which sells the drug under the trade name Miltown in the U.S. Carter originally licensed Fine Chemicals and Delmar Chemicals to manufacture the drug in Canada and to sell it to licensees of Carter as designated by Carter. Subsequently, Frosst was granted a compulsory licence under section 41(3) of the Patent Act. A number of other firms are now selling dosage forms of this drug, but whether this is being done under licence from Carter is not clear. Carter's Canadian subsidiary, N.S. Carter Products Limited,

which also represents Carter's ethical drug division (Wallace Laboratories Inc.) in Canada, does not sell the drug in Canada.

356. Delmar Chemicals reported that ". . . due to competitive pressure we discontinued production of this item." In 1958, it had reported that, in addition to manufacturing the drug, it purchased part of its requirements for resale from Fine Chemicals (at \$15.00 per kg.) and from Byron Chemical Company, New York (at an initial price of \$11.35 per kg. which dropped in stages to \$7.56 per kg.). Fine Chemicals is the principal Canadian supplier and supplies several of the large firms, including Ayerst and Wyeth which sell the widely used brands of Miltown and Equanil respectively. Meproamate is imported from American Roland Corporation, New York, by E. C. Godwin & Associates and resold to several Canadian companies. One custom manufacturer reported it buys prepared meproamate tablets (400 mg.) from Marsing & Co., Denmark, at a price of \$3.40 per thousand tablets. Both this firm and another custom manufacturer resell such tablets to other drug firms at \$6.25-\$6.50 per thousand.

357. Fine Chemicals reported that its selling price is \$9.00 per kg. The cost of the drug purchased through Godwin & Associates would appear to be below this figure, probably of the order of \$6.00. One large firm buys from its U.S. parent at \$29.12 per kg., but there are undoubtedly intercompany reasons for purchasing on this basis rather than at the lower price available in Canada. Fine Chemicals' selling price in 1958 was \$21.00 per kg., so the price of the drug has dropped by about 57 per cent since that time.

358. On the basis of a cost of \$9.00 per kg., the theoretical cost of the basic drug in 200 mg. tablets would be nine cents for 50 tablets, 90 cents for 500 tablets. In the 400 mg. tablets, the theoretical cost would, of course, be exactly twice these figures.

359. Selling prices of various firms were reported to be as follows:

Tablets - 200 mg.

		<u>Size</u>	<u>List</u> \$	<u>Retailer</u> \$	<u>Hospital</u> \$	<u>Hospital</u> <u>Quantity</u> \$
Neo Drug	Neo-Tran	50's	3.00	1.80*	1.62*	
Wyeth	Equanil	50's	4.00	2.40	2.07	
Elliott-Marion	Trelmar	50's	3.00	1.50*		
Neo Drug	Neo-Tran	500's	27.00	16.20*		
Wyeth	Equanil	500's	35.00	21.00	16.36	13.34
Elliott-Marion	Trelmar	1,000's	57.50	28.50*		
Neo Drug	Neo-Tran	1,000's			10.00	

Tablets - 400 mg.

Ayerst	Miltown	50's	6.00	3.60	2.95	
Elliott-Marion.	Trelmar	50's	5.50	2.75*		
Intra	Tranquiline	50's	5.00			
Neo Drug	Neo-Tran	50's	5.50	3.30*	2.97*	
Wyeth	Equanil	50's	6.00	3.60	2.95	
Dymond		100's	4.00	2.00*	2.00*	
Empire		100's		1.75		
Gilbert		100's		2.25		
McClung-Clemens		100's	3.25	1.95*	1.62*	
Ayerst	Miltown	500's	52.50	31.50	24.55	18.99
Dymond		500's	16.50	8.25*	8.25*	
Elliott-Marion.	Trelmar	500's	52.50	26.25*		
Empire		500's		7.50		
Intra	Tranquiline	500's	45.00		24.55	17.30
McClung-Clemens		500's	14.00	8.40*	7.00*	
Neo Drug	Neo-Tran	500's	49.50	29.70*		
Wyeth	Equanil	500's	52.50	31.50	24.55	18.99
Bell-Craig		1,000's		13.50		
Dymond		1,000's	32.00	16.00*	16.00*	
Elliott-Marion.	Trelmar	1,000's	100.85	50.43*		
Empire		1,000's		13.25		
Gilbert		1,000's		17.50		
McClung Clemens		1,000's	27.00	16.20*	13.50	
Neo Drug	Neo-Tran	1,000's			16.00	

360. On tenders to Departments of the Federal Government, the following prices have been quoted:

400 mg. Tablets - Bottles of 500 Tablets

Ayerst	\$10.35-\$18.95
Bell-Craig ...	2.39 - 4.05
Gilbert	2.68 - 2.9*
Intra	2.50 - 6.00
T. Milburn Co.	3.09

400 mg. Tablets - Bottles of 1,000 Tablets

Ayerst	\$10.35-\$36.78
Bell-Craig ...	5.00 - 9.90
Elliott-Marion	14.90 - 29.90
Gilbert	4.50 - 28.50
Intra	10.00 - 24.50
Wyeth	14.79 - 36.50

361. Oxanamide - Dosage forms of this drug are sold by Merrell under the trade name Quiactin. (The same company also sells a dosage form of oxanamide and another drug under the trade name Quen.) Prepared tablets are brought in from the United States (the company's operation in Canada is a branch only, not a subsidiary). The price to the Canadian branch is \$12.16 (U.S. funds) per thousand tablets. Selling prices were reported to be as follows:

Quiactin Tablets - Merrell

	<u>Size</u>	<u>List</u> \$	<u>Retailer</u> \$	<u>Hospital</u> \$
400 mg.	50's	6.00	3.06	2.75 ^x

The prices to a retailer and to a hospital are calculated on the basis of information about discounts allowed which was submitted some time ago. These discounts are larger than those usually allowed and may have been allowed to encourage sales of the drug when it was first introduced in February 1958. At that time, the list price was \$7.00. It has since been reduced to \$6.00.

362. Perphenazine - Dosage forms of this drug are sold by Schering under the trade name Trilafon. Dosage forms include tablets, ampoules, suppositories and syrup. Tablets are imported from Schering Corporation, New Jersey, as is the basic drug for the manufacture of syrup. Ampoules are made by Fine Chemicals and suppositories by Mowatt & Moore. The price which Schering pays its parent company for bulk perphenazine is \$1.96 per gram, including duty and transportation. The prices which it pays for tablets in bulk are:

2 mg. tablets	-	\$ 5.10	per 1,000
4 " "	-	9.18	" "
8 " "	-	17.72	" "
16 " "	-	34.76	" "

Selling prices of tablets will serve as an example and these were reported to be:

Trilafon Tablets - Schering

	<u>Size</u>	<u>List</u> \$	<u>Retailer</u> \$	<u>Hospital</u> \$	<u>Hospital</u> <u>Quantity</u> \$
2 mg.	50's	4.30	2.58 ^x		
	500's	37.90	22.74 ^x		
	1,000's			37.70	
	5,000's	352.30		169.65	
Purchases of 1,000,000					
per 1,000					17.72
4 mg.	50's	5.85	3.51 ^x		
	500's	45.45	27.27 ^x		
	1,000's			45.20	
	5,000's	422.60		203.40	
Purchases of 1,000,000					
per 1,000					21.29
8 mg.	50's	8.35	5.01 ^x		
	500's	70.70	42.42 ^x		
	1,000's			70.22	
	5,000's	656.50		315.99	
Purchases of 1,000,000					
per 1,000					33.12
16 mg.	500's	99.90			
	1,000's			99.50	
	5,000's			455.40	
Purchases of 1,000,000					
per 1,000					46.72

363. An interesting point is that it apparently does not cost much to prepare the tablet dosage form. Schering buys the bulk drug from its parent at \$1.96 per gram. It also buys tablets at various prices; if the 8 mg. tablets are taken as an example, the price is \$17.72 per thousand. One thousand 8 mg. tablets would total 8 grams so that the theoretical cost of the basic drugs in the tablets would be \$15.68. There is no way of knowing whether the U.S. parent company takes the same markup on the drug as on the finished tablets; however, it is supplying the Canadian company with the basic drug at \$15.68 and the same quantity of the drug in prepared tablets at \$17.72.

364. Phenaglycodol - Dosage forms of this drug are sold by Lilly under the trade name Acalo. Bulk quantities of prepared capsules are purchased by Lilly from its U.S. parent at 30 cents for the package of 20 capsules and 59 cents for the package of 50 capsules. Selling prices were reported as:

Acalo Pulvates - Lilly

	<u>Size</u>	<u>List</u> \$	<u>Retailer</u> \$	<u>Hospital</u> \$
300 mg.	20's	2.80	1.68*	1.51*
	50's	6.00	3.60*	3.24*
	1,000's		64.80	58.32*
(per 1,000)	5,000's		60.00	54.00*

The list prices of this drug have remained unchanged since its introduction in 1957.

365. Prochlorperazine - Dosage forms of this drug are sold by Poulenc under the trade name Stemetil. The basic drug is obtained by Poulenc from Société Parisienne d'Expansion Chimique (Specia), Paris, France, at a cost of \$259.72 per kg. Dosage forms include 5, 10 and 25 mg. tablets. Selling prices of these tablets were reported to be (see also explanatory notes on Poulenc's pricing policies under chlorpromazine above):

Stemetil Tablets - Poulenc

	<u>Size</u>	<u>List</u> \$	<u>Retailer</u> \$	<u>Hospital</u> \$	<u>Special</u> \$
5 mg.	50's	4.50	2.70	2.25	
	500's	35.00	21.00	17.50	
	1,000's	60.00	36.00	30.00	21.00
Purchases of 250,000					
per 1,000		42.00	25.20	21.00	
10 mg.	50's	6.00	3.60	3.00	
	500's	45.00	27.00	22.50	
	1,000's	80.00	48.00	40.00	30.00
Purchases of 250,000					
per 1,000		60.00	36.00	30.00	
25 mg.	50's	8.00	4.80	4.00	
	500's	60.00	36.00	30.00	
	1,000's	100.00	60.00	50.00	38.00
Purchases of 250,000					
per 1,000		76.00	45.60	38.00	

On the basis of the price of \$259.72 per kg., the cost of the basic drug in a 1,000 tablet package of 10 mg. tablets would be approximately \$3.00.

366. Promazine - Dosage forms of this drug are sold by several firms. In 1958, Wyeth reported that certain Canadian patents on promazine were held by Rhone-Poulenc. However, no other firm reported patents or licensing arrangements and Fine Chemicals reported that it had no arrangements with anyone in respect of its manufacture of the drug. It would appear that sale and distribution of the drug in Canada are not restricted by patent control.

367. The drug is manufactured in Canada by Fine Chemicals. It was formerly manufactured by Delmar, but its production proved to be uneconomic and was discontinued. Fine Chemicals' selling price to manufacturers at the end of 1959 varied from \$40.00 per kg. for one kg. to \$34.00 per kg. on purchases of 10 or more kg. One manufacturer imports from its parent in the U.S. and pays \$9.08 per pound (approximately \$20.00 per kg.). Another firm buys from Marsing & Co., Denmark, at a price of \$45.00 per kg. (This is a small firm and only small quantities may be involved.) A number of smaller firms buy prepared dosage forms from packagers. Prices paid were reported as \$2.45 and \$3.15 per thousand for 25 mg. tablets; \$3.40 and \$4.70 per thousand for 50 mg. tablets, and \$6.90 per thousand for 100 mg. tablets. Another firm reported that it pays 26 cents for 50, 25 mg. tablets, and 36 cents for 50, 50 mg. tablets, but this apparently covers the packaged, labelled product ready for resale. Selling prices were reported to be as follows:

25 mg. Tablets or Capsules

		<u>Size</u>	<u>List</u> \$	<u>Retailer</u> \$	<u>Hospital</u> \$	<u>Hospital</u> <u>Quantity</u> \$
Gama	Serenex	50's	4.00	2.00*	2.00 STI	
Intra	Intrazine	"	3.55	2.13*		
M. & M. ..	Pro-Tran	"	4.75	2.85*		
Will	Promwill	"	1.90	.95*		
Wyeth	Sparine	"	5.25	3.15	2.72	
M. T. C. .	Promazine	100's	4.00	2.00		
McCl. Cl.		"	2.10	1.26*	1.05*	
Winter ...		"		1.00		
Bell-Craig		500's		4.00		
Intra	Intrazine	"	32.35	19.41		
M. T. C. .	Promazine	"	13.00	6.50*		
M. & M. ..	Pro-Tran	"	42.00	25.20*		
McCl. Cl.		"	6.90	4.14*	3.45*	
Will	Promwill	"	16.00	8.00*		
Wyeth	Sparine	"	45.00	27.00	23.32	15.15*
Winter ...		"		4.20		
Bell-Craig		1,000's	25.00	7.00		
Intra	Intrazine	"	58.80	35.28*	18.18	
M. T. C. .	Promazine	"	24.00	12.00*		
Will	Promwill	"	30.00	15.00*		
Winter ...		"		6.90		6.80

50 mg. Tablets or Capsules

		<u>Size</u>	<u>List</u> \$	<u>Retailer</u> \$	<u>Hospital</u> \$	<u>Hospital</u> <u>Quantity</u> \$
Gama	Serenex	50's	6.50	3.25*	3.25	
Intra	Intrazine	"	5.70			
M. & M. ..	Pro-Tran	"	7.50	4.50*		
Will	Promwill	"	3.00	1.50		
Winter ...		"		1.80		
Wyeth	Sparine	"	8.00	4.80	4.15	
McCl. Cl.		100's	2.50	1.50	1.25*	
Winter ...		"		1.80		
Bell-Craig		500's		7.20		
Intra	Intrazine	"	51.75			
M. & M. ..	Pro-Tran	"	67.50	40.50*	37.12*	
McCl. Cl.		"	11.00	6.60*	5.50*	
Will	Promwill	"	27.00	13.50*		
Wyeth	Sparine	"	65.00	39.00	33.68	23.37*
Winter ...				7.50		
Bell-Craig		1,000's	40.00	13.25		
Intra	Intrazine	"	94.10			29.10
McCl. Cl.		"	21.00	12.60*	10.50*	
Will		"	56.00	28.00*		
Winter ...		"		13.50		

75 mg. Capsules

Ell.-Mar.	50's	6.85	3.43*
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100 mg. Tablets

M. & M. ..	Pro-Tran	50's	10.00	6.00		
Wyeth	Sparine	"	12.50	7.50	6.48	
Winter ...		100's		2.90		
Bell-Craig		500's		12.75		
M. & M. ..	Pro-Tran	"	90.00	54.00*		
Winter ...		"		13.00		
Wyeth	Sparine	"	99.00	59.40	51.30	32.25*
Bell-Craig		1,000's	65.00	24.00		
Winter ...		"		24.25		

368. On the basis of a price of \$34.00 per kg. for promazine, the cost of the basic drug in 50 tablets would be:

25 mg.	-	\$0.0425
50 "	-	0.085
75 "	-	0.1275
100 "	-	0.17

369. Reserpine - This drug is used as a tranquilizer drug and in the treatment of hypertension. It is widely used in combination with other drugs.

370. Reserpine is patented by Ciba, but apparently before the actual

granting of the patent, many other firms started to sell the drug and it was impractical to stop these firms from continuing to sell the drug after the patent was obtained. In the result, dosage forms of reserpine, and of reserpine in combination with other drugs, are sold by many firms.

371. Reserpine was formerly manufactured in Canada by Fine Chemicals, but that firm now imports the drug for resale. Laid-down cost to Fine Chemicals was reported as \$644.00 per kg. and its selling prices as:

Under 25 grams	-	\$1.50	per	gram
25-99 grams	-	1.40	"	"
100-249 grams	-	1.30	"	"
250 and over	-	1.20	"	"

Fine Chemicals supplies most of the smaller Canadian manufacturers. The larger companies buy from various sources, usually their parent or related companies. Prices appear to range from \$850.00 to \$1,500.00. The drug is sold in various strengths and, because of this, prices reported are sometimes confusing.

372. One common dosage form is tablets in 0.1 mg., 0.25 mg. and 1.00 mg. sizes. On the basis of a cost for the basic drug of \$1,200.00 per kg., the theoretical cost of the drug in 0.25 mg. tablets would be three cents for 100 tablets and 30 cents for 1,000 tablets. One small packager in Canada buys reserpine at \$1,400.00 per kg. and sells 0.25 mg. tablets to other manufacturers at 17 cents for a 100 tablet package and 68 cents for a 500 tablet package. Two small firms which buy prepared 0.25 mg. tablets in the United States reported costs of \$1.00 plus duty per 1,000 tablets and \$1.20 per 1,000 tablets (it is not clear if the latter price includes duty). Upjohn imports finished 0.25 mg. tablets from its parent at \$1.4¢ per 1,000.

373. Selling prices as reported vary widely. To illustrate this, only the prices for one size of tablet, 0.25 mg., is given, but the prices of most firms are shown:

		Size	List \$	Retailer \$	Hospital \$
S.K.F.	Eskaserp	30's	2.05	1.23*	1.05
Can. Pharmacal		50's	2.50		
Anca		100's	3.20	2.13	
B.D.H.		"	3.75	2.25*	
Ciba	Serpasil	"	4.55	2.73*	
Dymond		"	1.30	.65*	
Empire		"		.90	
Frosst	Alserin	"	3.75	2.25*	
Hartz	Serpone	"	1.33*	.79*	
Ingram & Bell.	Sertens	"	1.70	.92	.83
Intra		"	1.00	.60*	
Mowatt & Moore	Rauserpen-Alk	"	2.75	1.65*	
Nadeau		"	.80	.40*	
Neo Drug	Neo-Serp	"	3.00	1.80*	
Parke-Davis ..	Serfin	"	3.75	2.25	2.02
Pitman-Moore .	Ebserpine	"	1.50	.90	
Powell		"	2.55	1.275*	
Saunders		"		.70	
Upjohn	Reserpoid	"	4.53	2.71*	
Anca		500's	14.70	9.80	
B.D.H.		"	16.75	10.05*	
Can. Pharmacal		"	22.50		
Ciba		"	21.25	12.75*	
Dymond		"	4.30	2.15*	
Empire		"		2.20	
Frosst		"	16.75	10.05*	
Gama	Gamaserpin	"	13.50	6.75*	
Hartz		"	5.77*	3.46*	2.60
Ingram & Bell.		"	6.85	3.70	3.33
Intra		"	3.55	2.13*	
Mowatt & Moore		"	12.50	7.50*	
Nadeau		"	2.60	1.30*	
Pitman-Moore .		"	5.25	3.15*	
Powell		"	8.70	4.35*	
Saunders		"		2.70	2.16
Upjohn		"	21.18	12.70*	
Anca		1,000's	27.50	18.33	
Bell-Craig ...		"	12.50	7.50	
B.D.H.		"	32.50	19.50*	
Can. Pharmacal		"	44.00		
Dymond		"	7.50	3.75*	
Empire		"		3.75	
Frosst		"	32.50	19.50	5.75
Gilbert		"	15.00		3.75
Hartz		"	10.66*	6.38*	4.80*
Ingram & Bell.		"	11.90	6.43	5.79
Intra		"	6.30	3.78*	3.44
Nadeau		"	4.20	2.10	
Neo Drug		"	28.00	16.80*	2.50
Pitman-Moore .		"	9.50	5.70*	
Powell		"	15.40	7.70	
Saunders		"		5.00	4.00

374. Thioridazine - Dosage forms of this drug are sold by Sandoz under the trade name Mellaril. Tablets are purchased in bulk from Sandoz Ltd., Switzerland, at the following prices:

10 mg.	-	\$10.76	per 1,000 in bulk
25 mg.	-	13.80	" " " "
100 mg.	-	33.40	" " " "

Selling prices were reported as follows (prices to hospitals are decreased proportionately as the quantity purchased increases - only the lowest available quantity price is shown):

	<u>Size</u>	<u>List</u> \$	<u>Hospital</u> \$	<u>Hospital</u> <u>Quantity</u> \$
10 mg. tablets	100's	8.00	3.60	
	1,000's			3.24
25 mg. tablets	100's	10.00	4.50	
	500's	45.00	20.27	
	1,000's	80.00	36.00	
Purchases of over 100,000 per 1,000				27.44
100 mg. tablets	50's	12.50	5.63	
	500's	100.00	45.04	
Purchases of over 100,000 per 1,000				59.35

375. Triflupromazine - Triflupromazine hydrochloride is sold by Squibb under the trade name Vesprin and triflupromazine dihydrochloride is sold by Smith Kline & French under the trade name Stelazine. Both drugs are sold in various dosage forms. Squibb buys its drug from its parent at a landed cost of \$0.4554 per gram. Smith Kline & French buys tablets in bulk from its parent at the following prices:

1 mg.	-	\$1.15	per 1,000
2 mg.	-	1.32	" "
5 mg.	-	1.80	" "
10 mg.	-	3.10	" "

The theoretical cost of the basic drug in Squibb's tablets would be:

10 mg.	-	\$4.55	per 1,000
25 mg.	-	11.35	" "
50 mg.	-	22.77	" "

Selling prices were reported as:

		<u>Size</u>	<u>List</u> \$	<u>Retailer</u> \$	<u>Hospital</u> \$
(10 mg.)	Vesprin	50's	4.50	2.70	2.45
(1 mg.)	Stelazine	50's	4.75		2.45
	Vesprin	500's	42.50	25.50	23.18
	Stelazine	500's	43.00		22.10
(25 mg.)	Vesprin	50's	6.75	4.05	3.68
(2 mg.)	Stelazine	50's	6.25		3.20
	Vesprin	500's	63.00	37.80	34.36
	Stelazine	500's	57.00		29.25
(50 mg.)	Vesprin	50's	9.00	5.40	4.90
(5 mg.)	Stelazine	50's	8.80		4.50
	Vesprin	500's	85.00	51.00	46.36
	Stelazine	500's	83.75		43.00

Special prices to hospitals on quantity purchases are available. Squibb did not set out its special prices, but from information supplied by Smith Kline & French, it was calculated that the lowest quantity price would be (regular hospital price is given for purpose of comparison):

	<u>Size</u>	<u>Hospital Regular</u> ¢	<u>Hospital Quantity</u> ¢
1 mg.	500's	22.10	14.70*
2 mg.	500's	29.25	16.92*
5 mg.	500's	43.00	27.00*
10 mg.	500's	57.00	36.00

CHAPTER XVI

COMPARISON OF DRUG PRICES IN CANADA AND OTHER COUNTRIES

376. During hearings of the Kefauver Committee, evidence was given of prices paid for various drugs in various countries. The evidence given raised some excitement in the Canadian press which resulted in headlines stating:

"Drug Prices in Canada 'Highest'" - Montreal Gazette,
December 23, 1959.
"Drug Cost is Highest in World" - Toronto Globe & Mail,
December 23, 1959.
"Canada Pays Most for Drugs" - Winnipeg Free Press,
December 23, 1959.

377. The prices presented by the Kefauver Committee were collected by the U.S. Department of State through the American Embassies in the Spring of 1959. The American prices used as a comparison were taken from the American Druggist Blue Book, 1959-60. Tables XXXIV to XXXVIII inclusive are based on tables compiled by the Kefauver Committee from the information collected. The Canadian prices shown were checked against information received from Canadian sources and any variations are noted.

TABLE XXXIV

PREDNISONE

MERCK'S PRICES TO DRUGGISTS, COMPARATIVE UNITED STATES
AND FOREIGN, 1959, 5 MG. TABLETS, BOTTLES OF 100

<u>City and Country</u>	<u>Price to Druggist</u>
	\$
London, England	*7.53
Rio de Janeiro, Brazil	*14.15
Amsterdam, Holland ...	16.05
Vienna, Austria	*17.16
United States	17.90
Toronto, Canada	*20.80
Rome, Italy	*22.16
Colon, Panama	*22.99
Sydney, Australia	*24.00
Tokyo, Japan	27.78

*Calculated from price for 30.

**Calculated from price for 20.

~~XXX~~List prices shown in the Canadian Pharmaceutical Journal Price Book (for July 1959) were \$10.50 for 30 tablets and \$33.12 for 100 tablets. Assuming the druggist was allowed a 40 per cent discount, the calculated price per 100 tablets, based on the price of 30 tablets, would be \$21.00. The price to the druggist for a 100 tablet package (this size is listed) would be \$19.87.

TABLE XXXVA
COMPARATIVE U.S. AND FOREIGN PRICES OF TRANQUILIZERS, 1959,
CHLORPROMAZINE, 25 MG. TABLETS, 50'S

City and Country	Trade Name	Company Marketing	Price to	
			Druggist \$	Consumer \$
United States	Thorazine	Smith Kline & French	3.03	*5.05
Toronto, Canada	Largactil	Rhone-Poulenc	3.75**	7.05**
Sydney, Australia	"	May & Baker (British)94	1.69
Paris, France	"	Specia (Poulenc subsidiary)51	.77
Dusseldorf, Germany ..	Mogaphen	Bayer97	1.9*
Rome, Italy	Largactil	Farmitalia (owned 51 per cent by Montecatini, 49 per cent by Poulenc Shionogi & Co.	1.22	1.62
Tokyo, Japan	Wintermin	Yoshitomi Pharmaceutical	1.91	2.29
"	Contomin	Banyu Pharmaceutical Co.	1.88	2.28
"	Sevamine	Rhodia	2.14	2.57
Rio de Janeiro, Brazil	Amplictil	Specia	1.53	2.00
Brussels, Belgium	Largactil	"	1.37	1.96
Amsterdam, Holland ...	"	May & Baker	1.31	1.93
London, England	"		.77	**

*Computed from price to druggist at standard markup.
**The price to druggists for Largactil is as shown. However, the price to consumers is the price as set out in the then current College of Pharmacy Prescription Pricing Guide and includes a prescription fee. The manufacturer's list or suggested resale price was reported as \$6.25 (calculated from the list price of \$2.50 for 20 tablets).
***Not available.

TABLE XXXVB

COMPARATIVE U.S. AND FOREIGN PRICES OF TRANQUILIZERS, 1959,
PROCHLORPERAZINE, 10 MG. TABLETS, 50'S

<u>City and Country</u>	<u>Trade Name</u>	<u>Company Marketing</u>	<u>Price to</u>	
			<u>Druggist</u>	<u>Consumer</u>
United States	Compazine	Smith Kline & French	3.93	6.55
Toronto, Canada	Stemetil	Rhone-Poulenc	3.60*	6.75*
Sydney, Australia	Stemetil**	May & Baker	2.84	5.00
Paris, France	Tementil	Specia80	1.20
Dusseldorf, Germany	Nipodal	Bayer80	1.58
Brussels, Belgium	Stemetil	Specia	1.61	2.30
London, England	Stemetil**	May & Baker	2.24	***

6 Computed from price to druggist at standard markup.

* The price to druggists reported to the Director is as shown. The price to consumers is the price set out in the current Ontario College of Pharmacy Prescription Pricing Guide and includes a prescription fee. The manufacturer's list or suggested resale price for 50 Stemetil tablets was \$6.00

** Price reported to subcommittee for 5 mg. tablet has been doubled. (Pro rata conversion to 50 tablets per package by subcommittee staff where necessary.)

*** Not available.

TABLE XXXVI

COMPARATIVE UNITED STATES AND FOREIGN PRICES
OF MEPROBAMATE, 1959, 400 MG. TABLETS, 50'S

<u>Country and Seller</u>	<u>Trade Name</u>	<u>Price to</u>	
		<u>Druggist</u>	<u>Consumer</u>
		\$	\$
United States:			
Carter	Miltown	3.25	5.42
Wyeth (American Home).	Equanil	3.25	5.42
Argentina:			
Cyanamid	Miltown ^{xa}	.745	.8475
Austria:			
Cyanamid	Miltaun ^a	1.56	3.02
Petrasch (many others)	Meprobanat ^b	.60	1.18
Australia:			
Cyanamid	Miltown ^a	3.47	5.86
Wyeth	Equanil ^a	3.47	5.86
Imperial Chemical	Mepavlon ^c	2.81	4.69
Knoll Lab.	Pimal ^a	2.24	3.92
Brazil (Rio):			
Cyanamid	Miltown ^a	2.20	2.86
Wyeth	Equanil ^d	2.20	2.86
Belgium:			
Cyanamid	Miltown ^a	3.25	4.64
Imperial Chemical	Mepavlon ^d	1.75	2.50
Roter, Holland (many others)	Artolon	.91	1.30
Canada:			
Wyeth	Equanil	3.60 ^{xx}	6.75 ^{xx}
Ayerst (American Home)	Miltown	3.75 ^{xx}	7.05 ^{xx}
France:			
Byla	Equanil ^b	2.65	3.98
Germany:			
Cyanamid	Miltaun	.69	1.33
Asche (Wyeth)	Aneural ^e	1.36	2.78
Tropen Werke	Crypon	.66	1.30
Great Britain:			
Cyanamid	Miltown	1.48	-
Wyeth	Equanil ^b	1.41	-
ICI	Mepavlon ^c	1.45	-
Holland:			
Cyanamid	Miltown ^a	3.56	5.24
Wyeth	Quaname ^f	1.12	1.65
ICI (many others)	Mepavlon ^a	1.12	1.64
India:			
Lederle	Miltown ^a	4.79	5.99
Wyeth	Equanil ^b	4.25	4.73
Iran:			
Cyanamid	Miltown ^a	4.68	5.20
Wyeth	Equanil	3.55	3.95
Le Peitit	Per Tranquil	3.28	3.65
Wallace	Milinorm	3.60	4.00
Italy:			
Cyanamid	Miltaun ^c	1.77	2.36
Wyeth	Quanil ^d	1.94	2.58
Pierrel (many others).	I'axin ^g	1.33	1.77
Japan:			
Lederle	Miltown ^g	2.50	3.33
Banyu	Equanil	2.56	3.33
Mexico:			
Cyanamid	Miltown ^a	2.00	2.40
Wyeth	Equanil	1.80	2.18
Venezuela:			
Cyanamid	Miltown ^a	5.44	7.06
Wyeth	Equanil ^a	5.44	7.06

(footnotes overleaf)

Footnotes for Table XXXVI:

*Footnotes indicate that prices have been calculated for 50 from prices given for:

a	25 tablets
b	20 "
c	30 "
d	24 "
e	36 "
f	40 "
g	100 "

(Prices converted to dollars at official rate.)

~~50~~*The price to the druggist for Equanil is in accordance with the information supplied the Director. The price to the consumer is again the prescription price shown in the Ontario College of Pharmacy Pricing Guide. The manufacturers' list price is \$6.00. As in the case of chlorpromazine and prochlorperazine, meprobamate may only be sold on prescription in Canada and the consumer would actually pay \$6.75 if the druggist who filled the prescription followed the O.C.P. Pricing Guide. The information supplied the Director indicates Miltown is priced the same as Equanil and not as shown.

TABLE XXXVII

COMPARATIVE UNITED STATES AND FOREIGN PRICES OF
SPARINE, 1959, 25 MG. TABLETS, BOTTLES OF 50

<u>Country</u>	<u>Trade Name</u>	<u>Marketer</u>	<u>Price to Druggist</u> \$
United States	Sparine	Wyeth	3.00
Australia ...	Sparine	Wyeth Interna- tional	.94
Venezuela ...	Vipromazine	Wyeth	2.70
Germany	Verophen	Bayer	.83
	Protacyl	Asche	.80
Brazil	Promazionon	Wyeth ^x	1.26
Holland	Prazine	Wyeth	1.59
Canada	Sparine	Wyeth	3.15
Mexico	Liranol	Wyeth ^{xxx}	1.66
Italy	Liranol	Wyeth ^{xxx}	1.32

^xCalculated from price for 30 tablets.

^{xxx}Calculated from price for 20 tablets.

^{xxxx}Calculated from price for 25 tablets.

TABLE XXXVIII

COMPARATIVE U.S. AND FOREIGN PRICES OF SERPASIL,
1959, BOTTLES OF 100

<u>City and Country</u>	<u>0.25 mg. Tablets, Price to Druggist</u> \$	<u>1 mg. Tablets, Price to Druggist</u> \$	<u>Consumer</u> \$
United States	4.50	12.00	*20.00
Sydney, Australia	1.35	4.41	6.92
Vienna, Austria	1.03	2.78	5.03
Toronto, Canada	2.70	9.87	16.45
Paris, France83	1.21	1.82
Dusseldorf, Germany ..	^{xxx} 1.05	^{xxx} 3.42	^{xxx} 6.41
Amsterdam, Holland ...	1.09	xxxx	-
Bombay, India	xxxx	5.29	xxxx
Tokyo, Japan	xxx 1.75	5.56	6.94
Brussels, Belgium	^{xxx} 1.89	ø 4.24	ø 6.06
Rio de Janeiro, Brazil	^{xxx} 1.95	5.53	7.19
Tehran, Iran	xxxx	ø 4.87	ø 5.39
Rome, Italy	^{xxx} 1.83	øø 4.90	øø 6.48
Istanbul, Turkey	^{xxx} 2.52	xxxx	-
London, England	1.06	3.94	-
Caracas, Venezuela ...	^{xxx} 3.05	7.85	10.20

*Retail Fair Trade minimum.

^{xxx}Calculated from price for 40.

^{xxxx}Calculated from price for 50.

~~xxxx~~Not available.

~~ø~~Calculated from price for 30.

~~øø~~Calculated from 20.

378. The foregoing comparison relates only to prices of prednisone and certain tranquilizer drugs. A comparison of Canadian and United States prices for certain other drugs is given in Tables XXXIX and XL below. These deal with ethical drugs and with proprietary drugs and vitamin preparations respectively. It is emphasized that the comparisons are between prices of a product sold by a particular firm in the U.S. and the same product sold by a related firm in Canada. No attempt has been made to determine the general level of prices of a particular type of drug in each country since this appears to be impractical where there are numerous sellers offering at least roughly equivalent products at different prices. However, it is felt that the comparative prices in each country of precisely equivalent products give some indication of the level of drug prices in the two countries. The U.S. prices are taken from Drug Topics Red Book, 1960, which (as stated on the cover) was published in the Fall of 1959. Canadian prices are taken from the Canadian Pharmaceutical Journal Price Book, 19th Edition which shows prices as of November 1, 1959. Certain information has been taken from Canadian price lists but only when it appeared prices were those in effect in the latter part of 1959. The prices shown are therefore not necessarily current prices but are prices which were in effect in the United States and in Canada in the latter part of 1959. In some cases, difficulty was experienced in checking sizes and other particulars, but it is believed that the information shown is correct. Table XXXIX, dealing with ethical drugs, gives comparative prices, where available, for the antibiotic and tranquilizer drug products dealt with in Chapter XV above. Table XL gives comparative prices of a number of proprietary drug and vitamin products about which information of selling prices, sizes and the like, for both countries was available. The selection of items for inclusion in the table was on a random basis.

TABLE XXXIX

LIST PRICES OF SELECTED ETHICAL DRUG PRODUCTS IN
CANADA AND IN THE UNITED STATES (AS OF LATE 1959)

(Antibiotic Drugs)	<u>Size</u>	<u>U.S.</u>	<u>Canada</u>
<u>Penicillin G Potassium</u>		\$	\$
100,000 I.U. - tablets			
Abbott - Abbocillin	100's	9.17	14.10
250,000 I.U. - tablets			
Parke-Davis	12's	2.50	2.75
	100's	18.30	-
<u>Penicillin V (various types)</u>			
200,000 I.U. - 125 mg.			
Abbott - Compocillin VK	50's	15.00	17.15
Lilly - V Cillin	50's	15.00	17.00
400,000 I.U. - 250 mg.			
Abbott - Compocillin VK	25's	12.50	15.40
Lilly - V Cillin	24's	12.00	
	12's		7.50
<u>Dihydrostreptomycin</u>			
Parke-Davis	1 gm.	.50 ^x	.77
	5 gm.	1.85	3.40
(*based on price of \$2.50 for 5)			
<u>Broad-Spectrum Antibiotic Drugs (various types)</u>			
250 mg.			
Bristol - Tetrex	16's	8.50	9.44
	100's	51.00	56.60
Cyanamid - Aureomycin	16's	8.50	9.44
	100's	51.00	56.61
Parke-Davis - Chloromycetin	16's	8.50	9.45
	100's	51.00	56.70
Pfizer - Terramycin	16's	8.50	9.44
	100's	51.00	56.61
Cyanamid - Achrostatin V	16's	9.33	10.19
	100'	55.84	60.55
Squibb - Mysteclin V	16's	9.33	10.19
	100's	55.83	60.55
<u>Erythromycin</u>			
250 mg.			
Lilly - Ilotycin	24's	12.70	14.00
	100's	51.00	56.10

TABLE XXXIX (Cont'd)

<u>Bacitracin</u>	<u>Size</u>	<u>U.S.</u> \$	<u>Canada</u> \$
50,000 I.U. - vial			
Upjohn		6.00	8.02
<u>Cycloserine</u>			
250 mg.			
Lilly - Seromycin	40's	16.80	19.50
	500's	193.30	233.34
<u>Kanamycin</u>			
500 mg.			
Bristol - Kantrex	20's	16.80	17.66
	100's	79.20	84.76
<u>Neomycin</u>			
500 mg.			
Upjohn - Mycifradin	20's	16.50	17.67
	100's	79.15	84.77
<u>Novobiocin</u>			
250 mg.			
Merck - Cathomycin	16's	8.05	11.62
	100's	48.33	71.20
Upjohn - Albamycin	16's	8.06	11.60
	100's	48.33	71.13
<u>Nystatin</u>			
500,000 I.U.			
Squibb - Mycostatin	12's	1.47	1.95
	100's	11.67	14.60
<u>Oleandomycin</u>			
250 mg.			
Hoffmann-La Roche - Romicil	16's		9.45
	100's		56.60
Pfizer - Matromycin	16's	8.50	
<u>Ristocetin</u>			
500 mg. - vial			
Abbott - Spontin		5.42	7.35
<u>Vancomycin</u>			
500 mg. - 10 cc. ampoule			
Lilly - Vancocin		7.00	10.60

TABLE XXXIX (Cont'd)

	<u>Size</u>	<u>U.S.</u> \$	<u>Canada</u> \$
<u>Viomycin</u>			
Ciba - Vinactane	1 gm.	3.07	3.95
	5 gm.	13.03	16.70
(Tranquilizer Drugs)			
<u>Benactyzine HCL</u>			
Merck - Suavitil	1 mg. 100's	5.40	
Horner	2 mg. 100's		3.15
	3 mg. 100's		4.75
<u>Captodiamine HCL</u>			
Ayerst - Suvren	50 mg. 100's	5.50	6.75
	100 mg. 100's	9.50	12.00
<u>Chlormezanone</u>			
100 mg.			
Winthrop	100's	11.67	12.50
	1'000's	110.00	117.50
<u>Chlorpromazine (see above)</u>			
<u>Deserpidine</u>			
Abbott - Harmony1	0.1 mg. 100's	3.80	2.55
	0.25 mg. 100's	6.38	4.55
	1 mg. 50's	8.75	8.60
<u>Ectylurea</u>			
300 mg.			
Ames - Nostyn	48's	5.85	7.25
	500's	56.00	67.00
<u>Ethchlorvynol</u>			
Abbott - Placidyl	100 mg. 100's	2.67	3.00
	200 mg. 100's	3.75	4.20
	500 mg. 100's	5.42	6.00
<u>Hydroxyzine</u>			
Pfizer - Atarax	10 mg. 100's	6.06	6.16
	25 mg. 100's	13.66	13.82
<u>Meproamate(see above)</u>			
<u>Cyanamide</u>			
400 mg.			
Merrell - Quiactin	50's	6.50	6.00
<u>Perphenazine</u>			
Schering - Trilafon(prices to retailers only are available and are shown*)			
	2 mg. 50's	2.55	2.58
	500's	24.05	22.74
	8 mg. 50's	4.25	5.01
	500's	40.25	42.42

* See transcript of Hearings - Volume 1, pages 30-31.

TABLE XXXIX (Cont'd)

<u>Phenaglycodol</u>	<u>Size</u>	<u>U.S.</u> \$	<u>Canada</u> \$
300 mg.			
Lilly - Acalo	20's		2.80
	50's		6.00
Lilly - Ultram	100's	10.45	

Prochlorperazine (see above)

Promazine

Wyeth - Sparine (prices to retailers
only are available and are shown.)

25 mg.	50's	3.00	3.15
	500's	28.75	27.00
50 mg.	50's	3.60	4.80
	500's	34.20	39.00
100 mg.	50's	4.80	7.50
	500's	46.30	59.40

Reserpine

Ciba - Serpasil	100's	7.50	4.55
Upjohn - Reserpoid	100's	6.38	4.53

Triflupromazine

25 mg.			
Squibb - Vesprin	50's	6.05	6.75
	500's	57.00	63.00
2 mg.			
Smith Kline & French - Stelazine	50's	6.55*	6.25

(*calculated from price to retailer.)

TABLE XL

LIST PRICES OF PROPRIETARY DRUGS AND VITAMIN PRODUCTS
IN CANADA AND IN THE UNITED STATES (AS OF LATE 1959)

	<u>Size</u>	<u>U.S.</u> \$	<u>Canada</u> \$
Absorbine, Jr.	4 oz.	1.25	1.19
	12 oz.	2.50	2.39
Agarol (plain)	6 oz.	.85	.85
	16 oz.	1.49	1.50
Alka-Seltzer	8's	.35	.39
	25's	.65	.78
Anacin	12's	.25	.26
	30's	.53	.53
	50's	.73	.85
	100's	1.19	1.29
Antiphlogistine	5 oz. jar	.69	.75
	8 oz. tube	.98	1.19
	16 oz. jar	1.49	1.64
	5 lb. can	4.75	4.75
Ayds	3 lbs.	5.50	5.58
Bantron	15's	1.25	1.50
Bayer Aspirin	12's	.15	.20
	24's	.25	.32
	48's		.53
	50's	.39	
	100's	.69	.87
Beecham's Pills		.50	.65
Benzedrex Inhaler		.75	.85
BiSoDoL Mints	30's	.29	.35
	100's	.69	.98
Bromo-Seltzer	Small	.33	.33
	Regular	.65	.63
	Family	.98	.98
Bufferin	12's	.25	.39
	36's	.59	.79
	60's	.83	1.23
	100's	1.23	1.89
Castoria		.49	.53
		.79	.85
Castor Oil (Squibb)	3 oz.	.45	.48
Cod Liver Oil (Squibb)	4 oz.	.59	.80
	12 oz.	1.29	1.70
Dodd's Kidney Pills	40's	.60	
	35's		.69
Dolcin Tablets	100's	2.00	2.49
	200's	3.50	3.95
	500's	8.00	8.95

TABLE XL (Cont'd)

	<u>Size</u>	<u>U.S.</u> \$	<u>Canada</u> \$
Dristan Nasal Mist	15 cc.	1.19	1.25
" Tablets	24's	.58	1.25
	50's	1.69	2.25
	100's	2.89	3.75
Eno Fruit Salts	Regular		.79
	Large		1.19
Eno Sparkling Antacid	Medium	.75	
	Large	1.25	
Ex-Lax	6's	.15	.21
	18's	.37	.49
	48's	.79	.87
Feen-A-Mint	5's	.15	
	6's		.21
	16's	.37	.49
	36's	.69	.87
Foot Powder, Dr. Scholl's	3½ oz.	.40	.50
	8 oz.	.75	1.00
Freezone	Large	.39	.53
Geritol, liquid	4 oz.	1.25	1.35
" junior	8 oz.	2.00	2.25
" liquid	12 oz.	3.00	3.29
" "	24 oz.	5.00	5.49
" Tablets	14's	1.25	1.35
	40's	3.00	3.29
	80's	5.00	5.49
Heet Liniment	2¼ oz.		.79
	2-1/3 oz.	.69	
	5 oz.	1.19	1.29
Infrarub	1.1 oz.		1.39
	1.33 oz.	.98	
	3.3 oz.	1.89	2.49
Ironized Yeast Tablets	60's	.89	1.25
	120's	1.49	2.00
	240's	2.49	3.35
Kriptin Tablets	12's	.39	.49
	50's	.98	1.25
Lavoris	4 oz.	.40	.40
	9 oz.	.65	.70
	17 oz.		1.25
	20 oz.	1.00	
Listerine	3 oz.	.37	.39
	7 oz.	.59	.73
	14 oz.	.89	.98
Lysol	2 oz.	.29	.45
	5 oz.	.59	.83
	12 oz.	.99	1.50
Mentholatam	1 oz.	.45	
	Small		.59
	3 oz.	.90	
	Large		1.19

TABLE XL (Cont'd)

	<u>Size</u>	<u>U.S.</u> \$	<u>Canada</u> \$
Mentholatum Rub	1 $\frac{1}{4}$ oz.	.90	.98
	3-1/3 oz.	1.70	
	Large		1.89
Midol Tablets	5's	.17	
	6's		.25
	12's	.34	.47
Mothersills Remedy, Adult's	Small	.75	.79
	Large	1.50	1.59
" " Children's		.75	.79
Nature's Remedy, Regular	25's	.25	.29
	60's	.50	.59
	180's	1.00	1.19
Nujol	8 oz.	.43	.59
	16 oz.	.69	.89
	32 oz.	1.09	1.49
Pertussin Cough Syrup	4 oz.	.79	.75
	8 oz.	1.19	1.25
Phillip's Milk of Magnesia	4 oz.	.29	.33
	12 oz.	.57	.67
	26 oz.	.89	1.13
Preparation H	1 oz.	.98	1.19
	2 oz.	1.69	1.98
Raz-Mah (Brown)	24's		1.65
	25's	1.50	
	104's		5.00
	125's	5.00	
" (Grey)	30's	1.50	1.65
	130's		5.00
	150's	5.00	
Resulin Lotion	4 oz.	2.00	2.55
Sal Hepatica	2.4 oz.	.35	.45
	6.0 oz.	.69	.89
	10 oz.	.99	1.09
Scott's Emulsion	Small	1.00	1.00
	Large	1.80	2.00
Capsules	96's	3.50	3.00
Sloan's Liniment	2 $\frac{1}{2}$ oz.	.60	
	Small		.75
	6 oz.	1.20	
	Medium		1.25
Unguentine	1 oz.	.75	.75
	2 oz.	1.25	1.25
	16 oz.	3.50	3.50
<u>Vitamins</u>			
Abbott - Dayalets-M	100's	6.54	6.95
	250's	15.45	16.30
Ayerst - Beminal, Plain	100's	2.85	4.00
	1,000's	24.50	33.00

TABLE XL (Cont'd)

	<u>Size</u>	<u>U.S.</u> ¢	<u>Canada</u> ¢
Cyanamid - Filibon	100's	5.25	5.85
Vi-Tyke Syrup	4 oz.		2.00
	12 oz.	3.50	
Hoffmann-La Roche -			
Vi-Penta Perles	25's		1.50
	100's		4.75
Vi-Penta Perles Forte	25's	1.45	
	100's	4.35	
Lilly - Mi-Cebrin	30's		4.40
	60's	4.35	
	100's	6.65	12.75
Multicebrin	100's	5.65	6.70
	1,000's	53.00	64.15
Miles - One-A-Day Multiple	25's	1.00	1.49
	50's		2.75
	60's	2.00	
	100's	3.00	4.49
	250's	6.60	8.75
Parke-Davis - Myadex'	30's	3.30	
	50's		6.95
	100's	10.75	12.85
Pfizer - Viterra	100's	5.83	6.05
Upjohn - Zymacap	100's	6.60	9.75
U.S. Vitamin Corporation (Arlington-Funk Laboratories) -	50's	2.65	3.75
Vi-Aqua	100's	4.75	6.95
	500's	22.00	32.50
Wyeth - Vitules	100's	4.89	5.35

CHAPTER XVII

SUMMARY

General

379. Drugs are sold to the public in dosage form. A dosage form may consist of only one drug (with any necessary binder, diluent, etc.) or of a combination of drugs.

380. Drugs are classified as ethical and proprietary drugs. This classification is related to the legislation dealing with drugs, the general effect of which is that certain drugs may not be advertised to the general public, may only be sold to the general public through licensed pharmacies and, in the case of many such drugs, may only be sold on the prescription of a doctor, dentist or other person authorized by law to prescribe drugs. Such drugs are referred to as ethical drugs and are those drugs which the proper authorities feel should not be used indiscriminately by the public but should only be available under proper supervision and control. Proprietary drugs, strictly speaking, are drug products the formulae of which are registered under the Proprietary or Patent Medicine Act, but in ordinary usage the term includes those common drugs and household remedies which are not subject to the same restrictive controls as ethical drugs. While, as explained, even these drug products are subject to certain regulations, in general they are advertised and sold freely.

381. This inquiry has been concerned almost entirely with ethical drugs and the following comments are intended to apply to such drugs unless otherwise stated.

Control of the Sale of Drugs

382. The sale and distribution of drugs are controlled by both Federal and Provincial legislation. There is some overlapping. For example, both Provincial and Federal legislation contain provisions setting out which drugs may only be sold on prescription. However, in the main, Provincial legislation deals with such matters as the qualifications of pharmacists, the licensing of pharmacists, the operation of drug stores, the types of drugs which may only be sold to the public through drug stores, the classes of persons (doctors, dentists, etc.) who may prescribe drugs, and similar matters. Federal legislation deals mainly with the quality of

drugs, the types of drugs which may be sold only on prescription, and the advertising of drugs to the public. The legislation in each Province sets up a governing body which supervises the practice of pharmacy, the operation of drug stores and related matters within the Province. The principal body administering the Federal legislation is the Food and Drug Directorate of the Department of National Health and Welfare. The functions of the Directorate have been outlined above.

Use of Chemical, Generic and Trade Names

383. A drug may be referred to by its chemical name or by its generic name. The chemical name, which is frequently long and complicated, is descriptive of the composition of the drug. The generic name is the commonly accepted name as, for example, penicillin, chloramphenicol, meprobamate or reserpine.

384. Wide use is made of trade names in the drug field. Primarily, these serve the same purpose as in any other field, that is, a trade name identifies a product of a particular firm. However, trade names are used in a somewhat different way than in most other fields. Instead of using one trade or brand name for its line of products, a drug firm usually uses a trade name for each particular drug which it sells. The main purpose of using a trade name is to have the trade name displace the chemical or generic name. To the extent that this is accomplished, the trade-named product is specified when the drug is required as, for example, when a doctor prescribes the drug. It should be noted that when a prescription specifies a particular trade-named product, the pharmacist is bound to supply that product and cannot substitute another brand (unless he has obtained the consent of the doctor who wrote the prescription). If, on the other hand, the prescription simply specifies the drug, the pharmacist may supply any brand of the drug which is available. The extent to which trade names are used can be gathered from the arrangement of reference books which almost invariably give equal prominence to trade names as to generic names and index all drugs by trade names. It may be noted that, while the names used are registered trade names, the usual practice in the industry is to refer to them as brand names.

385. Normally large, long-established ethical drug firms use trade or brand names while smaller and less well-known drug firms sell certain

drugs under their generic names. Normally, too, the smaller manufacturer sells at lower prices. Because of these two facts, it has been suggested that if doctors would prescribe drugs by generic names, the public would pay considerably less for having prescriptions filled.

386. This is an oversimplification of the situation. In the first place, it raises the question of the comparative quality of the products of different manufacturers. As suggested above, the so-called "generic versus brand name" controversy is a misnomer; the real controversy is about the quality of the products of large established manufacturers as compared with those of small firms, an issue which is complicated by various sub-issues such as the importation and use of drugs from foreign sources. Although constant inspections of drugs are carried out, it has not been practical to inspect every batch of every drug sold in Canada. This has opened the door to criticism of the products of smaller manufacturers since it is impossible to prove categorically that such products are of an equivalent quality to those of the manufacturers which enjoy established reputations for the quality of their products. Regardless of the merits of such criticism (about which no opinion is expressed), it is undoubtedly effective. A doctor's primary concern is with the quality of the drug which he prescribes and price is a secondary consideration. A cheap drug under a generic name and of equal quality to a brand-named product may be available, but unless a doctor is personally satisfied of this fact he is likely to prescribe the brand-named product. In this connection, it may be noted that the Food and Drug Directorate is presently studying changes in the regulations relating to both the sale of imported drugs and the manufacture of drugs in Canada. These changes are designed to provide stricter control over the manufacture of drugs in Canada and the testing and inspection of drugs imported into Canada.

387. In the second place, there may be practical difficulties in obtaining a particular product under a generic name. Very broadly, drugs may be classified into three groups: those widely available from numerous suppliers, specialties of particular firms, and drugs controlled by patents. In respect of widely available drugs, products under both brand and generic names can be obtained freely. But in the case of these products, the

advantage of buying the product under its generic name will be slight. A brand-named product may be sold at a premium price but, simply because there are so many alternatives available, the premium will be small. In respect of patented products and specialties, the difficulty is to obtain these products under generic names. Some patented drugs are available from importers but, subject to this, both patented drugs and specialties are normally available only from the patent holder or the developer of the specialty. (Specialty is here used in the sense of a unique combination developed by one firm and not duplicated precisely by any other firm. Patented products are also specialties, but for a different reason, viz., that the patent control prevents other firms dealing in the particular drug.) Moreover, in the case of a patented drug, an importer is likely to offer only a standard dosage form, while the patentee is likely to offer a wide variety of dosage forms. Thus, in those cases where it might be expected that maximum savings would be effected by purchasing under the generic name, since the brand-named product is usually high priced, it may not be possible to obtain the desired product under the generic name. (It should be noted that brand-named products also invariably carry the generic or chemical name, although the brand name is much more conspicuous on the package. A doctor could, for example, prescribe "Equanil" or "meprobamate, Wyeth" and the same product, i.e., meprobamate sold by Wyeth under the brand name Equanil, would be supplied in either case.)

388. Finally, comments on this matter based on conditions in the United States must be accepted with caution because of the much greater number of products on the market there. An examination of price books shows that, in the United States, where a drug is not controlled by patents, there are almost invariably a very large number of suppliers offering a myriad of alternative products. An example, which does not relate to the ethical drug field, will nevertheless illustrate the situation. The public acceptance of the product Metrecal has drawn comment in the press and elsewhere and, in referring to it, Life Magazine, January 6, 1961, mentioned that at least forty similar products were being marketed in the United States. Maclean's Magazine January 28, 1961, also referred to the same product but stated that it was one of five similar products being marketed in Canada. This

appears to be typical and obviously quite different considerations will apply to the question of generic versus brand names where the number of alternative products available is much greater.

389. The foregoing is not intended to suggest that savings cannot be effected by prescribing drugs by their generic names, but rather that the situation is involved and simply having doctors prescribe by generic names is not the complete solution to high drug prices it is sometimes represented to be. Available information indicates that savings by purchasing drugs under their generic names have been realized chiefly by Government or institutional buyers who buy in large quantities and who are able to test the quality of the drugs which they purchase.

Sales Tax

390. A few drugs, such as cortisone, are not subject to sales tax but sales tax is payable on most drugs. One very important exemption relates to public hospitals. Drugs purchased by public hospitals and not resold by them (as by a specific charge to a patient for drugs used by him) are exempt from sales tax. Because drugs administered in hospitals are included in the services furnished under most of the Government-financed hospital plans now in operation, presumably most ethical drugs sold to hospitals come within the exemption. Proprietary or patent medicines appear to be specifically excluded under most plans.

Tariff

391. Some drugs (or material used in the preparation of drugs) are not subject to duty, but most are subject to duty, when imported, with the rate of duty depending on the country of origin, whether the drug is of a class or kind made in Canada, the form in which the drug is imported and similar considerations. While each drug is in a sense unique, speaking very generally, dosage forms are usually classified as of a class or kind made in Canada on the basis of their general purpose. To take a simple example, a drug sold as a laxative might not be manufactured in Canada, but there are numerous laxatives manufactured in Canada, so that the particular drug, especially if it is imported in a semi-prepared or prepared dosage form, would probably be classified as of a class or kind made in Canada. The importance of this is in the application of dumping duties. Every product

imported into Canada (assuming it is dutiable) is subject to duty on its fair market value in the country of origin, although it may be invoiced at a lower price. But if it is of a class or kind made in Canada, it must be invoiced to the importer at its fair market value. If it is invoiced at a lower price, dumping duties are applied to bring the cost to the importer up to the fair market value. Where the product is imported in the same form in which it is sold in the country of origin, the fair market value is the selling price to a corresponding class of purchaser in the country of origin. Where the product is imported in a semi-prepared form, say by a subsidiary from its parent, there are usually no similar sales in the country of origin to determine fair market value. In such cases, a markup which is set after considering all the circumstances, is applied to the cost of manufacture. Thus, in the case of one product for which particulars are available and which is imported in large drums, the fair market value has been fixed by adding 75 per cent to the cost of manufacture. In other cases, the markup to establish fair market value is very small and, in still other cases, intermediate markups are used. The seller will, of course, charge the purchaser at least the fair market value. If the seller charges a lower price, the purchaser will simply have to pay the difference in dumping duties. Charging the fair market value means that the additional amount charged is secured by the seller rather than being paid in duties.

392. The provisions of the Customs law relating to dumping duties are particularly important in relation to dealings between Canadian subsidiaries and their foreign parent firms. Most foreign parent drug firms are in the business of supplying the consumer through regular trade channels rather than supplying other drug manufacturers. The fair market prices of their products, as determined by actual sales, are therefore the prices charged jobbers or wholesalers. The Canadian subsidiary buying at these prices may be in the position of buying at virtually the same price as that at which it sells. The position will vary from product to product and will depend on whether the product is imported in a final prepared dosage form ready for resale, or in an intermediate form which requires further manufacture or preparation in Canada. To the degree that the price charged by a foreign parent company to a Canadian subsidiary

approaches the trade price in the country of origin, profit is taken by the parent rather than by the subsidiary. In an extreme case, such as that referred to in the letter quoted in Chapter III above, the Canadian subsidiary may sell at a loss, but it is obvious that the regular profit on the particular product had already been taken by the parent company. This means that profits of Canadian subsidiaries are not an accurate indication of the actual profit resulting from the sale of imported drugs; they reflect the earnings of the Canadian subsidiary only and do not reflect any profit previously taken by the parent company.

Patents

393. Patents are important in the drug field. In the case of a drug produced by a chemical process, only the method of producing the drug, or the drug when produced by that method, may be patented in Canada. Subject to this restriction, which means that only a process patent may be issued in respect of such drugs, drugs may be patented in Canada. Many drugs, and particularly the newer antibiotic and ataraxic drugs, are the subjects of patents (process or product, as the case may be) and the manufacture, importation and sale of these drugs in Canada are controlled by the holders of the patents or their licensees. As has been noted in the Statement, a few small firms have obtained supplies of certain patented drugs from abroad and have sold such drugs in Canada without licence arrangements with the holders of the patents. Apart from this, patented drugs are available only from the patent holders and their licensees. It has been the practice of patent holders to restrict the number of firms dealing in many patent controlled drugs. Instances of where a particular drug is sold by only one or a few firms have been noted above.

394. The Canadian patent legislation provides for compulsory licences to manufacture under patents relating to food and drugs, and both the practice of the Patent Commissioner and the decisions on appeals from his rulings to the courts indicate that such compulsory licences will be issued in appropriate cases. Nevertheless, advantage has been taken of the provisions relating to compulsory licensing under patents on drugs in only a few instances.

395. One explanation suggests itself. Most of the large ethical drug firms in Canada are subsidiaries or branches of foreign companies, many of

which carry on world-wide operations. These firms have developed their own specialties which they promote in whatever countries they do business. It may not be considered practical for such a firm to obtain a compulsory licence which would only allow it to manufacture and sell a particular drug in Canada. If it did so, its Canadian subsidiary or branch would have to develop and market the product on its own in competition with established brands of manufacturers which would, for example, be advertised in the United States technical and scientific journals which reach Canadian doctors. It does seem to be significant that the few compulsory licences issued under section 41(3) of the Patent Act have been obtained chiefly by wholly Canadian firms.

396. There is also the possibility that firms desiring licences may be reluctant to apply for compulsory licences under the Patent Act because of difficulties and delays which may be encountered. For example, the evidence of an official of Connaught Medical Research Laboratories given before the Select Committee on Drugs of the Ontario Legislature seems to indicate that he held this view and that it was shared by others in the drug manufacturing field (Transcript, pp. 1024-25). While the situation appears to have been clarified by recent decisions interpreting the compulsory licensing provisions, undoubtedly those in the industry are influenced by their knowledge of difficulties and delays which were encountered in the past.

397. The opinion was expressed to the Director that a compulsory licence from an unwilling licensor may not be nearly as valuable as a negotiated licence. This is because a licensor which has been forced to grant a licence may withhold technical "know-how" and knowledge acquired from its experience in producing the drug in question. This might be an important consideration in deciding if a compulsory licence should be sought.

398. There are similar provisions regarding compulsory licensing in England and it has been suggested that the implied threat that these may be used has been sufficient to induce patent holders to grant licences.*

*The Structure of British Industry, Burns et al, Vol. 2, pp. 351-52.

The Ilsley Commission expressed the view that this was also true in Canada.* Whatever may be the situation in England, the information available to the Director does not indicate that the compulsory licensing provisions in the Canadian patent law have induced patent holders to grant licences freely under their drug patents.

399. Virtually all the antibiotic and tranquilizer drugs were developed outside Canada and Canadian patents are held chiefly by foreign firms. If, as has been the case in several instances, conflicting claims have arisen, these claims have usually been settled in the country where the drug was developed and the Canadian patents reflect the settlements. Considerable detail about patent claims, litigation and settlements in connection with patents on antibiotic drugs is given in the FTC Economic Report on Antibiotics Manufacture. The information given in the Report shows that arguments about patent rights were settled in the United States and information supplied to the Director shows that patents in line with the settlements (except that some would be process rather than product patents) were obtained by the respective firms in Canada.

Extent of Manufacture of Basic Drugs in Canada

400. The sources of supply and the extent to which manufacture of basic antibiotic and ataraxic drugs is carried on in Canada have been reviewed in the Statement. It is clear that most are imported into Canada. This is as might be expected since these drugs are new and the distribution of any particular drug is largely channelled through the firm holding the patent. The patent holder and its licensees, if any, are normally not interested in selling to other manufacturers. In most cases such drugs are marketed in Canada by a branch or subsidiary and it is probably more convenient and economical for the parent company to supply the drug rather than to set up separate manufacturing facilities in Canada.

401. General information indicates that many other basic drugs (besides

*Report on Patents of Invention, Royal Commission on Patents, Copyright and Industrial Designs, 1960, p. 95:

"It is probable that the number of compulsory licences ordered under our present section 41 is not indicative of its significance. It is generally considered that the mere existence of such provisions leads to voluntary licensing which otherwise would not take place."

those controlled by patents) are not manufactured in Canada because of the high cost of manufacture in this country. Officials of Connaught Medical Research Laboratories expressed the opinion informally that Canada cannot compete on a cost basis in the manufacture of basic drugs and that, except in the field of vaccines, Canada was now importing basic drugs which it had formerly manufactured. It will be remembered that, according to information supplied by Fine Chemicals, that firm is now importing reserpine whereas it formerly manufactured this drug in Canada. Since the submission of returns of information, manufacture of penicillin and streptomycin in Canada has been discontinued.* In general, it appears that the more complicated basic drugs are largely imported. Many of the commoner basic drugs are manufactured in Canada. A partial list of such drugs is given in Memorandum D51-33, dated June 8, 1960, of the Customs and Excise Division of the Department of National Revenue, and subsequent amendments to this Memorandum, copies of which will be supplied to the Commission.

Extent of Manufacture of Dosage Forms of Drugs in Canada

402. The foregoing comments relate to basic drugs. In respect of dosage forms of drugs, particulars of the situation regarding antibiotic and ataraxic drugs have been set out above. For the industry as a whole (and including related products besides ethical and proprietary drugs) the situation is indicated by the following tables from the D.B.S. publication, The Medicinal and Pharmaceutical Preparations Industry. Table XLI shows the value of the different types of products produced in 1958. Table XLII shows production, imports and exports respectively for the years 1949 to 1958 inclusive. Table XLIII shows the value of different types of products imported and exported. As indicated by the notes to the tables, Table XLI gives data for the firms reporting in this industry classification, the other tables include data from companies in other fields which produce some products in this field.

*See the explanatory statement that manufacture in the sense of refining crude penicillin is still carried on in Canada, Drug Merchandising, January 1961, p. 29.

TABLE XLI

PRODUCTS MADE IN THE MEDICINAL AND PHARMACEUTICAL
PREPARATIONS INDUSTRY, 1958

<u>Product</u>	<u>Value of Factory Shipments</u>
	\$
Medicines and pharmaceuticals:	
Registered as patent medicines and sold without all ingredients declared	23,915,783
Antibiotics and preparations:	
Penicillin preparations	3,485,102
Streptomycin preparations	379,656
Penicillin-streptomycin combinations	1,041,028
Other antibiotics and preparations thereof*	13,023,490
Sex hormones	3,017,526
Sulphonamide (sulpha) preparations with or without other active ingredients	2,239,069
Vitamins and preparations:	
Vitamins in bulk	xx
Vitamin preparations in which the principal active ingredients are vitamins	16,377,241
Biologicals and vaccines	8,788,324
Oral antiseptics	1,083,336
Ethical specialties for human use, not else- where specified	48,980,902
All other human medicines	11,966,506
Veterinary medicines	2,649,318
Disinfectants	255,614
Insecticides	490,890
Flavouring extracts	436,664
Toilet preparations	7,268,695
All other products ^{xxx}	9,607,037
Total	<u>\$155,006,181</u>

* Includes penicillin, streptomycin and other antibiotics as well
as antibiotic preparations not elsewhere specified.

xx Included with "All other human medicines".

xxx Includes soap, packaged goods, fountain supplies and syrup and
other such articles.

Source: D.B.S., The Medicinal and Pharmaceutical Preparations
Industry, 1958, p. 6.

[Note: Data given in this table are for the Medicinal and
Pharmaceutical Preparations Industry only and represent
only the production of the firms classified to this group.
For the total Canadian output of medicinals see Table
XLII.]

TABLE XLII

PRODUCTION,* IMPORTS AND EXPORTS OF MEDICINAL
AND PHARMACEUTICAL PREPARATIONS, 1949-58

<u>Year</u>	<u>Production^{xx}</u> (selling value at factory) \$	<u>Imports</u> \$	<u>Exports</u> \$
1949	64,816,801	14,828,906	3,885,464
1950	69,324,508	18,629,257	4,297,654
1951	82,131,000	22,427,000	6,037,000
1952	81,432,000	21,780,000	5,088,000
1953	87,098,000	22,417,000	5,659,000
1954	90,799,000	24,981,000	5,476,000
1955	100,878,000	24,599,000	4,248,000
1956	110,002,000	26,121,000	5,349,000
1957	126,297,000	28,392,000	6,835,000
1958	139,621,000	29,248,000	9,560,000

*Production figures represent the total Canadian production, including some medicinals made in other industries.

^{xx}Factory shipments since 1952.

Source: D.B.S., The Medicinal and Pharmaceutical Preparations Industry, 1958, p.8.

TABLE XLIII

IMPORTS INTO CANADA AND EXPORTS OF MEDICINAL AND
PHARMACEUTICAL PREPARATIONS, 1958

		<u>Quantity</u>	<u>Value</u> \$
<u>(a) Imports</u>			
Caffeine, and salts of	lb.	186,916	402,128
Cocaine	oz.	1,308	16,155
Codeine, and salts of	"	121,413	600,329
Opium derivatives, n.o.p.	"	10,601	49,697
Opium	lb.	-	-
Quinine, salts of	oz.	78,946	24,728
Strychnine, and salts of	"	11,731	9,868
Preparations or chemicals, weed-killing	3,121,319
Nicotine, salts of nicotine; preparations containing nicotine in a free or combined state, for dipping, spraying or fumigating, n.o.p.	lb.	47,730	37,145
Chloropicrin, ethylene oxide, methyl bromide, methyl formate, cyanides, carbon bisulphide, or mixture containing any of these, for combating destructive insects or pests	66,520
Preparations or chemicals, non-alcoholic, such as are used for disinfecting, dipping, spraying or fumigating, when in packages not exceeding three pounds each in weight	469,495
Preparations or chemicals, non-alcoholic, for disinfecting, dipping, spraying or fumigating, n.o.p., or manufacturing the same	8,397,337
Medicinal, chemical and pharmaceutical preparations, including proprietary preparations, dry	7,633,144
Medicinal, chemical and pharmaceutical preparations, including proprietary preparations, liquid, when containing not more than 2½% of proof-spirit	1,814,397
Medicinal, chemical and pharmaceutical preparations, including proprietary preparations, all other	195,559
Menthol, natural or synthetic	236,939
Papaine	42,980
Spirits and strong waters of any kind, mixed with any ingredient or ingredients, and being known or designated as anodynes, elixirs, tinctures or medicines, n.o.p.	gal.	25,766	245,141
Non-alcoholic extract of cascara sagrada	26,393
Penicillin, and products of	753,887
Streptomycin, and products of	173,555
Sulpha drugs	499,427
Antibiotics, n.o.p.	4,431,941
Total imports	29,248,084
<u>(b) Exports</u>			
Dipping, spraying and insecticide compounds	154,554
Penicillin, and products of	7,173
Streptomycin, and products of	92,610
Antibiotics, n.o.p.	195,365
Medicinal and proprietary preparations	9,110,401
Total exports	9,560,103

Note: "n.o.p." means "not otherwise provided for"
in the statistical classification.

Source: D.B.S., The Medicinal and Pharmaceutical
Preparations Industry, 1958, p. 11.

Influence of Conditions in the Drug Industry
in the United States

403. Conditions in the drug industry in Canada are related to and are influenced by conditions in the industry in the United States; in fact, in many respects the Canadian market may be considered as simply an extension of the United States market. The first reason for this is the dominance of the Canadian market by United States firms, a situation which applies to all drug products, proprietary as well as ethical. Not only are the dominant drug firms in Canada branches or subsidiaries of United States firms, but the influence of these firms appears to affect the policies of other foreign firms operating branches or subsidiaries in Canada. Specifically, the United States and Canadian drug markets are characterized by high prices - probably the highest in the world. When European and other firms enter this market, they appear to adopt the price levels prevailing in the market, regardless of the prices at which they may sell their products in other areas of the world. For example, as shown in Table XXXVA above, which is based on information obtained by the Kefauver Committee in the United States, the comparative prices in 1959 of fifty 25 mg. chlorpromazine tablets as sold in France by Specia (a subsidiary of Rhone-Poulenc), in the United States by Smith Kline & French (under licence arrangements with Rhone-Poulenc) and in Canada by Poulenc (a subsidiary of Rhone-Poulenc), were as follows:

<u>Country</u>	<u>Trade Name</u>	<u>Price to Druggist</u> \$	<u>Price to Consumer</u> \$
Canada	Largactil	3.75	6.25*
United States	Thorazine	3.03	5.05
France	Largactil	.51	.77

*As explained above, the Canadian price shown by the Kefauver Committee was \$7.05, but this included the prescription fee set out in the Ontario College of Pharmacy Pricing Guide.

Thus, the Canadian price reflects the usual relationship between Canadian and United States prices, but is not related to the price charged in France where the drug was developed and from where supplies of the basic drug are obtained.

404. Another reason for the influence of conditions in the United States drug industry is the special characteristics of drug products. The practice in the industry is to promote and sell products under brand names. Doctors

become familiar with the brand names of those products promoted to them. Because United States firms (usually through branches or subsidiaries) are so active in the Canadian market, their products are the best known and hence the most widely used. In the case of patented drugs, the brand-named products are (subject to the minor exceptions noted) the only dosage forms of the drugs available. To a lesser extent and varying somewhat from product to product, the same is true of specialties. If a doctor wishes to prescribe a particular combination of drugs, he may have no practical choice but to prescribe a brand-named product of one of the large firms such as Abbott, Lilly or Upjohn. Most of the patented products and specialties of such companies have been developed in the United States and, simply as the result of these firms supplying such a large part of the Canadian market, their products are widely used in Canada. There are certain other factors which, while intangible and difficult to measure, are probably quite important. The drug industry in the United States is very large and carries on a great deal of research and development. New drugs and new dosage forms of older drugs are constantly being developed and marketed. These are promoted in the usual way to doctors and reported in scientific and similar journals. The Canadian doctor receives essentially the same promotional material as the United States doctor. Moreover, as in other fields, the number and variety of scientific journals dealing with the medical field which are published in the United States greatly exceed the number published in Canada. These are seen and read by Canadian doctors. Hence, the Canadian doctor is subjected to a constant barrage of information and promotion about drug products developed in the United States but which are available in Canada through branches or subsidiaries of the United States developers. In these circumstances, it is only to be expected that Canadian doctors will rely heavily on such products.

405. There are various other factors and conditions which contribute to the close relationship of the Canadian drug industry to the drug industry in the United States. Conditions tend to be parallel. In summary, it appears that American drug products (which may be manufactured by a branch or subsidiary in Canada) are by far the most widely used and that, when firms from other foreign countries enter the Canadian market, they price their

products at the level of prices prevailing in this market. This price level appears to reflect the level of prices in the United States. Basically, United States products sold in Canada are priced the same in Canada as in the United States, but the application of sales tax in Canada means that the price to the consumer is about eleven per cent higher. The exact difference between Canadian and United States prices varies from product to product as will be noted from particulars set out in other parts of this Statement.

Competition at the Manufacturing Level

406. Competition in the drug field differs from competition in most other industries. In the case of ethical drugs which are normally prescribed by a doctor, the doctor, who determines which drug will be used, does not pay for it, while the patient, who does pay for it, has no part in choosing the drug. Moreover, price is likely to be a minor consideration in the doctor's choice. The doctor's primary concern is to prescribe the drug which will be most effective.

407. Because of the wide use of trade names, when a doctor decides on a particular drug he is likely to prescribe it by a trade name. This, of course, means that he prescribes the product of a particular firm. Subject to the considerations outlined above, in some instances the doctor has a choice and can prescribe the drug by its generic name if he wishes. But in respect of patented drugs or of dosage forms which combine several drugs, the doctor may have no choice. Except in the case of standard and widely used combinations which demand forces them to supply, firms try to develop combinations which are unique. Many are similar, but if a doctor wants a particular combination he may find that he must prescribe a specific product of a specific firm. It is not practical to have druggists prepare combinations of the newer and more complex drugs. These must be prepared at the manufacturers' level and only those so prepared are available.

408. Because of these considerations, competition among drug manufacturers consists largely of attempting to develop new products and of promoting their respective brand-named products to doctors. Each firm attempts to convince doctors of the merits of its particular products. Emphasis is laid on the trade name of each product so that the doctor will

prescribe any product he decides to use by its trade name. Price is not an important element in these forms of competition because promotion to doctors is rarely based on the price level of a product.

409. Some price competition among manufacturers does exist in respect of older and more widely available drugs. The effects of such competition on prices and availability of the older types of penicillin and of the streptomycins in the United States are extensively documented in the FTC Economic Report on Antibiotics Manufacture. In brief, prices were driven down to a point close to the costs of production. Canadian prices reflected a similar trend. But even in such cases the result is usually two levels of prices: one charged by the established ethical drug houses and a lower price charged by smaller drug firms. The prices charged by the established ethical drug houses for their brands of such older drugs are not in any sense exorbitant, but they are, nevertheless, higher than those of smaller manufacturers for similar products.

410. It would appear that the larger drug manufacturers have in recent years attempted to avoid a repetition of the experience with penicillin and the streptomycins, and any manufacturer discovering a new drug has sought to control its sale and distribution. In this they have been largely successful and this accounts for the different pattern of prices in the case of different drugs. Nevertheless, while certain drugs have been controlled successfully for some years, others have for various reasons become more widely available to manufacturers and price competition has developed. Such price competition is usually reflected first in special prices to hospitals. Where a drug is available from a number of equally reliable suppliers, hospitals will presumably buy from the cheapest source. These special prices to hospitals are usually followed by general reductions in price, but while it is difficult to generalize, it is clear that there is not the same competitive pressure on prices of the same products sold through regular trade channels.

411. Direct price competition to the established manufacturers is offered, on certain drug products, by smaller, less well-known firms. The principal appeal of such firms is on a straight price basis since they are normally only duplicating products already available from established

manufacturers. They are usually not able to compete in the manufacture and sale of the newer drugs which are protected by patents (except where such drugs are obtained from foreign sources), and do not have the facilities to develop or promote their own specialties. The experience of these firms appears to underline the importance of other factors than price in competition in the field. Despite the fact that their products are much cheaper than those of the established firms, these small firms have, to date at least, secured only a small share of the market and their low prices have not had any significant effect on prices of comparative products sold under trade names by established manufacturers. This is clearly due to the fact that their products are not generally accepted by doctors.

412. In the result, competition among manufacturers of ethical drug products takes the form of research to develop new products or new dosage forms of known drugs and intensive promotion by each firm of its products with particular emphasis on trade names. Price competition among established firms occurs chiefly in prices quoted to hospitals and in prices quoted in tendering to bodies, such as Federal Government departments, which purchase drugs under generic names so that price rather than trade name is important, and then only in respect of drugs offered by several manufacturers. On balance, and regardless of what other benefits may result from the competitive practices which are characteristic of the industry, it seems clear that these practices tend to increase rather than decrease the selling prices of drugs. Subject to the minor qualifications mentioned, there is virtually no price competition in the sale of patent controlled drugs and ethical drug specialty products.

Costs, Markups and Profits of Manufacturers

413. Discussion of costs, markups and profits of drug manufacturers has been widespread, particularly since the publicity following hearings before a Committee of the United States Senate. The evidence brought out before that Committee has been used to support widely different arguments. On the one hand, it is claimed that fabulous profits are being made by drug manufacturers. On the other hand, it is said that figures quoted to support such a conclusion are taken out of context and give a distorted

picture. Much of the argument, on both sides, seems to be designed to support a particular point of view. The following comments are made to suggest that some of these arguments must be examined with care.

414. One of the main justifications urged for present drug prices is the amount spent by manufacturers on research. Obviously, the cost of genuine research is a legitimate expense and one from which the public derives great benefit. Criticism has been directed at certain aspects of the manufacturers' research programmes. It has been suggested that some research is directed towards finding saleable variations of known drugs and that such research neither adds to present knowledge nor benefits the public; in fact, it is argued by some that it simply results in an unnecessary and wasteful duplication of products. Again, it is suggested that certain so-called research and clinical testing is really a form of promotion designed not to add to knowledge about the product being tested, but rather to secure publicity for the product and particularly the manufacturer's trade-named brand of the product. Undoubtedly, some of this criticism is justified, but it should not be allowed to obscure the benefits that do result from genuine research. However, the prices charged for drugs, in so far as such prices reflect the recovery of the cost of research, will be expected to bear some reasonable relationship to such cost. The argument which takes the form that research costs justify any prices, without considering the relationship between the two, is obviously unsound. Moreover, it is not true, as appears to be suggested by some apologists for the drug industry, that all research is carried on by the drug manufacturers and that all the benefits from the development of newer and better drugs are the result of research by drug manufacturers and particularly by United States manufacturers.

415. Another aspect of the cost of research is that, for a particular company, the cost of research may, in effect, be borne by one or two drugs. Figures reported for Schering (on its United States operations), for example, indicate that sales of that company totalled just under twenty million dollars annually before the development by it of the drugs prednisone and prednisolone. Within a few years after the development of these drugs (and almost entirely due to them) sales by the company increased to eighty million

dollars annually. Company profits increased and expenditures on research were expanded. Thus, the profits on these drugs were used, in part, not only to recoup past expenditures which resulted in the development of these drugs, but for a greatly expanded research programme on other drugs. The same pattern can be traced in other instances. It is accepted in the industry that the successful drugs pay for the failures.

416. Another commonly advanced general argument is that prices of drugs have only increased by a small percentage over a period of years. One figure frequently cited is that of the United States Bureau of Labor which reported a 19.1 per cent increase in the United States from the base period of 1947-49 to 1958. However, it has already been noted that one large company, Smith Kline & French, reported that 60 per cent of its sales are of products less than three years old and 80 per cent of its sales are of products less than six years old. In the case of this company, at least, the comparison of present prices with 1947-49 prices is meaningless because the same products are not involved.

417. A related argument which is somewhat inconsistent with the last argument is that prices of drugs have been drastically reduced. Penicillin is frequently cited as an example, but the credit here does not belong to the drug manufacturers. Cortisone is an example of such a price reduction by improved methods of manufacture developed by drug manufacturers. The benefits conferred on the public by the private drug manufacturers, first in developing cortisone and related drugs and then in reducing their cost of production, are not to be depreciated. But the fact that prices have been cut drastically due to improved methods of production tells us nothing about the reasonableness of present prices. In the light of present cost of production and the resources required in the industry, present prices may or may not be reasonable.

418. It is frequently stated that because of the efficacy of modern drugs, the total cost for illness to a patient is less. The patient may pay \$25.00 for antibiotics, but if he is saved from spending several weeks in hospital and loss of earnings during that period, he may be better off by several hundred dollars. This is quite true, but again it tells us nothing

about the reasonableness of the price of the antibiotic.

419. A variation of this argument is that the public spends less on drugs than on liquor or motor cars. Once again, while this is certainly true, it tells us nothing about the reasonableness of the price of drugs.

420. Some or all of these arguments are relevant to such questions as the comparative cost of drugs in relation to other commodities, or studies as to proportion of family income spent on drugs, or the like. These matters are important, but they are distinct from the question whether or not prices of particular drug products are high in relation to the minimum prices at which they could be supplied to the public.

421. Details of costs and selling prices of certain drugs are given in Chapter XV above. As will be noted, the costs and the selling prices of various drugs differ widely, as does the relationship between the manufacturer's selling price and the prime cost of the drug, i.e., the cost of purchasing or preparing the dosage form itself without taking into account promotional, selling and similar costs.

422. As has been pointed out, costs reported to the Director by manufacturers depend, in many cases, on the price which a foreign parent charges the Canadian branch or subsidiary for either the basic drug or the prepared or semi-prepared dosage form. These costs reflect arranged prices in the sense that the price charged by the parent may be either higher or lower than the price which would be paid by a firm buying in the open market. In many instances, it is not possible to obtain comparative open market prices.

423. It should be noted that the cost of dosage forms is not necessarily directly proportional to the cost of the basic drugs used because of the variation in quantities used. For example, a typical price charged by Fine Chemicals for meprobamate sold to other manufacturers is \$9.00 per kg. One of the common dosage forms of this drug is the 400 mg. tablet. Theoretically, one kg. of meprobamate would be sufficient for 2,500 tablets. For reserpine, a typical price would be \$1.30 per gram or \$1,300.00 per kg. Common dosage forms of this are 0.25 and 1.0 mg. tablets. Theoretically, one kg. of reserpine would be sufficient for four million 0.25 mg. tablets or one million 1.0 mg. tablets. Thus, while reserpine costs about one

hundred and forty-four times as much as meproamate as a basic drug, tablets of meproamate (400 mg. size) would contain an amount of that drug which would cost ten times as much as the reserpine contained in an equal number of reserpine tablets (0.25 mg. size).

424. The information available to the Director indicates that broad general statements about the costs or selling prices of drugs generally have little meaning. Drugs fall into various classes related to the availability of the drug to manufacturers generally, control over the drug exercised through patents, development of specialty products, and similar factors. Regardless of what criterion is used to assess markup over cost, the situation varies from class to class and, to a lesser extent, from product to product within a class. All that can be said is that, in relation to prime cost, the selling prices of and the markup taken on newer patented drugs are substantially higher than on commoner and older drugs. Similarly, the selling prices of and the markups taken on established specialty products are normally somewhat higher than those taken on more standard products. At the other extreme, many drug firms carry products for which there is a very limited demand and on sales of which, for this or other reasons, they lose money.

425. The drugs about which particulars are given in this Statement are principally newer drugs and are among the highest priced and most profitable drugs sold by the manufacturers. They are not typical of drug products generally. Reference has been made above to the tremendous impact on a company's sales and earnings which can result from the discovery and marketing of a new drug which is widely accepted. It is the practice to set the price of such a drug high in relation to prime cost. This is done to recover costs of research, of promotion and similar expenditures as well as to ensure profits. It is not denied, even by the manufacturers, that this is done. Rather, it is contended that the practice is both necessary and desirable to ensure continued progress in the drug field. The potential reward awaiting any firm which discovers a new and better drug is said to be an incentive which stimulates research to find such a drug; the profit which follows the discovery of such a drug provides funds for continued and expanded research,

426. The information available about the profits of ethical drug firms

in Canada does not disclose the rate of profit as a return on investment. As in other fields, profits vary from firm to firm and, in the case of a few firms, profits are quite high.

427. In general, the level of profits as a percentage of sales in the ethical drug industry is above the level of profit in most other industries. It appears clear that profits on certain drugs, particularly specialties and patented products, are much higher than on drugs generally. It is difficult to draw any general conclusions about proprietary drugs because most firms manufacturing or distributing proprietary products usually also sell toiletries or other related lines as well.

428. The whole picture is further complicated because of the number of subsidiaries or branches of foreign firms which operate in Canada.

429. In the Canadian drug field, Frosst and Horner, which are Canadian companies, and Ayerst, which while now a subsidiary of an American company was originally a Canadian company, are among the large firms. These three firms, along with the Canadian branches or subsidiaries of the ten firms which have the largest sales in the United States (based on sales figures for 1959)^x, are the thirteen largest firms in the ethical drug field in Canada^{xx}. All thirteen have annual sales in excess of four million dollars each and are the only ethical drug firms in Canada having sales of this magnitude. This illustrates the extent to which the Canadian market is supplied with drugs by subsidiaries or branches of foreign firms which, as explained, obtain a large proportion of the drugs which they sell from parent or related companies. The fact that Canadian branches and subsidiaries rely so heavily on foreign sources of supply makes it necessary to be careful in appraising the reported costs of such firms. As already pointed out, the price charged by a parent to a subsidiary may be an arranged price in the sense that it may not be the same price which

^xIn an address reported in the New York Journal of Commerce on March 17, 1960, John T. Connor, President of Merck & Co., Inc., reported that the ten drug companies in the United States having the largest sales in 1959 were, in order, Lilly; Upjohn; Smith Kline & French; Cyanamid; Parke-Davis; Wyeth; Merck; Squibb; Abbott, and Pfizer.

^{xx}Since Connaught Medical Research Laboratories is not a commercial firm in the usual sense, it is not considered here,

the parent would charge an independent firm; in other words, it may not be a true market price in the normal meaning of the term.

430. It is obvious, too, that the operating costs and profits of a subsidiary company are likely to be affected by the fact that it is a subsidiary. Any company operating wholly-owned subsidiary companies will normally try to manage the affairs of both the parent and subsidiaries so as to maximize profits. Considerations of efficiency or economies of size or of scale may result in certain operations being handled by one firm for the group. Other considerations may make it advantageous for the supplying firm to take a large markup in some cases, while in other cases it may be more advantageous for the supplying firm to sell to related firms at prime cost so that the related firms take most of the markup. One company reporting to the Director pointed out how customs regulations tended to distort costs of drugs to the Canadian company on the one hand, while on the other hand general administrative costs and research and other costs borne by the parent company tended to distort general expenses so that these were shown as less than they actually were. It is clear that it is dangerous to draw firm conclusions based solely on the earnings or profitability of one of a group of related companies. Many of the companies from which information was obtained in this inquiry are subsidiaries or branches of foreign companies and this must be kept in mind in appraising the information submitted.

Alleged Wasteful Expenditures

431. Whatever may be said about the profits of manufacturers, the criticism which many informed observers direct against the industry is not against high profits as such. Rather, it is that firms in the industry engage in costly and at least partially unnecessary promotional and other activities which inflate their costs and make it necessary for them to charge prices which are high in comparison to the actual cost of manufacturing or preparing the drugs. The situation is aggravated because the prices of the older drugs have been reduced by competitive and other factors, so that these costs and expenses must be recovered from drugs which are specialties and whose prices can be controlled. Consequently, the latter drugs bear a disproportionate share of such costs and are marked-up to

recover such costs and to ensure the overall profit of the firm. The main criticisms relate to promotional practices; the creation of a multiplicity of essentially similar dosage forms and combinations; and the concentration in some research on the development of saleable products rather than on the advance of scientific knowledge.

432. Because ethical drugs are not advertised directly to the public, advertising and promotion take a somewhat different form than in other industries. Advertisements are published only in scientific, technical and trade publications which do not normally reach the general public. These are supplemented by other forms of promotion. Chief among these are the use of detail men; the practice of mailing promotional and informative literature to doctors; and the practice of distributing samples. Promotion in the industry is quite costly as has been illustrated by figures set out above.

433. It is argued that the dissemination of information about drugs to doctors by the use of detail men and direct advertising is necessary so that doctors will have up-to-date information.

434. The development of new drugs and the discovery of additional information about known drugs have been proceeding at a rapid pace in recent years. Reports on drugs and on the results of studies connected with drugs are constantly being published in various journals. Eventually, after a drug is developed and evaluated, particulars about it are published in the standard reference works. There are also works published yearly which serve as reference books as, for example, New and Nonofficial Drugs, published by the Council on Drugs of the American Medical Association. This publication, while a useful source of information, does not review all new drugs nor does it generally consider combinations of drugs. It does not compare drugs on the basis of cost or efficacy. There does not seem to be any concise, complete and current source of information about drugs available to a practising doctor who, obviously, would not have the time or facilities to keep abreast of all current medical literature. This is the lack which the drug manufacturers purport to satisfy through detail men and informational literature. It can only be said that this service is undoubtedly useful in some respects. On the other hand, it is costly and

has been subject to severe criticism on the grounds that the information supplied tends to be favourable information about the product which the drug manufacturer is promoting and that, in any event, much of it is more promotional than informative. Some general comments which were published in The Canadian Medical Association Journal have been referred to above.*

435. The creation of a multiplicity of dosage forms is an aspect of drug merchandising which has been criticized, particularly by medical authorities. The comments in the article from The Canadian Medical Association Journal referred to above will serve as an illustration. The value of various combinations of drugs is a medical question and is beyond the scope of this Statement. It is, however, important to define the exact nature of the criticism. It is not suggested that a particular drug should only be sold by one firm. Most standard drugs are available from a number of sources and the fact that different firms constantly compete to supply the demand for these drugs ensures that adequate supplies at a reasonable cost are available. Many forms of the older penicillins, for example, are and have been available from different suppliers (frequently under generic names even in the case of products of the large firms) and this has undoubtedly been a factor in the steady downward trend of prices of such products. The practice which is criticized is that of producing combinations which are only slightly different from the basic drug or from other combinations already on the market and promoting these new combinations, almost invariably under trade names, as new and important developments. Some medical authorities feel that the practice is carried to extreme and that

*The following is an extract from an article, "The Strange Ethics of the Ethical Drug Industry" by Alek A. Rozental, which appeared in Harper's Magazine for May 1960, p. 84:

"About a year ago, there appeared a remarkable publication, the Medical Letter. This journal attempts to review critically the claims made for some of the new drugs and to compare their cost and effectiveness with existing remedies. It frequently makes sharp comments. In its one year of existence, the publication, which does not accept advertising, has acquired over 13,000 subscribers. But, as one of them put it to me, those who do read the Letter generally need it less than those who either never heard of it or if they did, would distrust or dislike its aims. In any case, all that the editors of the Letter can do is to review the existing literature and sift the wheat from the chaff. They do not conduct their own tests and, whenever the existing evidence is inadequate, must withhold judgment."

the expense of development and of promotion of many such products is wasteful.

436. The criticisms of expenditures on research which are made by various critics are not directed towards research as such but rather at expenditures classified as research which are allegedly directed towards producing saleable products or the promotion of existing products. It is claimed such expenditures neither increase knowledge nor add new products of any significant value. Most of this discussion necessarily relates to practices in other countries, since only limited research is carried on in Canada. This seems to be because, if a firm is a branch or subsidiary of a foreign firm, such research as the firm carries out is likely to be done by the parent company in the country where its largest operations are centered. In the case of purely Canadian firms, most are too small to carry on research on a significant scale. Fresst, Horner and Ayerst are exceptions. Fresst and Horner are the largest Canadian ethical drug firms. Ayerst was, at one time, a purely Canadian operation and, while it is now owned by American Home Products Corporation, it had established research facilities in Canada before the firm was purchased by U.S. interests.*

437. It is important to note that, while research carried on in Canada is limited, Canada obtains the benefit (as it does in many other fields) of research done in other countries. Most of the leading drug firms in the world have either branches or subsidiaries or have agents in Canada which sell products that have been developed elsewhere. Whatever questions may arise about the cost of research reflected in the prices charged for drugs in Canada or similar aspects, these considerations should not be allowed to obscure the fact that all important new drugs are normally available through Canadian suppliers within a short time of their development.

Cost of Quality Control

438. One type of expenditure which is frequently advanced as a justification for the higher prices charged by established ethical drug firms is the alleged high cost of quality controls maintained by such firms. On the basis of the information obtained by the Director and reviewed above, the cost of maintaining controls to safeguard the quality of the drug

* In an article in Fortune Magazine for April 1958, "Alvin Brush's Specialty House", it is said that American Home Products Corporation (of which Alvin Brush is Chairman) became interested in and subsequently acquired Ayerst because the latter firm had developed a hormone preparation, Premarin. This drug, which is one of the firm's specialties, was developed in Canada.

products which such firms manufacture is not a large factor in the total cost of such manufacture. However, even though these expenditures are only a small factor in total cost of manufacture, they appear to be higher in the case of the large ethical drug houses and, to the extent that this is so, increase the basic costs of such firms.

The Importance of Patents in Relation to
Prices of Drugs

439. While the considerations which lead to certain drugs being high priced in relation to prime cost are varied and in some respects the subject of controversy, the fact that makes it possible for the manufacturers to charge high prices for such drugs is the control exercised through patents. In almost any field, a brand-named product of a manufacturer which enjoys a reputation for the quality of its products can normally be sold at a premium price. This seems particularly true in the drug field where quality of product is so important. Nevertheless, the premium which the manufacturer can command, on the basis of brand name alone, is relatively limited. But when the manufacturer holds a patent on the drug, it and its licensees, if any, have a complete monopoly on the drug and can set prices at whatever level they see fit. Patents also have an effect on specialties. While the situation varies from drug to drug, a common pattern is for a new drug to be made available first in dosage forms of the drug itself. Then, various modified dosage forms, frequently involving combinations with other drugs, are developed. In the course of time, new drugs may be developed which will largely supplant the basic drug; but the special dosage forms are likely to remain on the market and to be used long after the main dosage form has lost ground to other drugs. A writer in Fortune Magazine* for August 1958, described this phenomena in relation to Schering's "Meti" drugs (Meticorten and Meticortelone), but his comments would be equally true of many other drugs. He said, in part:

"If it is a competitor's product that supersedes the Metis, Schering will by no means lose all its gains of the last three years. About 35 per cent of the company's Meti-steroid sales are in the form of special preparations and combination drugs. Special preparations include salves, liquids, and sprays used for treatment of eye and skin disorders, for example. Combination drugs are

*"Schering's Structural Roulette", Fortune Magazine, August 1958, p. 104.

steroids combined with an analgesic, for nonspecific aches and pains, or with an antihistamine, for such allergies as hay fever.

These preparations take time to develop and establish, but once established they have a long career. Schering will probably hold a good part of its Meti special-preparation and combination sales for a considerable time after any new corticosteroid is successful. . . ."

Another example appears to be afforded by Terramycin (oxytetracycline) sold by Pfizer. In the beginning, the 250 mg. capsule was the standard and most widely used dosage form. Then, various other dosage forms, including intramuscular and intravenous injections, two types of ophthalmic ointment, a topical ointment, an otic solution, and various syrups, drops, powders and tablets were developed. Oxytetracycline has been supplanted to a large extent by tetracycline, and the oxytetracycline now sold is usually sold as a combination with glucosamine under the trade name Cosa-Terramycin. The interesting point is that Pfizer has now discontinued the 250 mg. capsule of Terramycin, which was formerly the standard dosage form, but continues to sell the special dosage forms which were developed. Presumably this reflects a continued demand for these products despite the lack of demand for Terramycin as such. It may be noted, too, that various special dosage forms of Cosa-Terramycin are being offered and, if previous experience is repeated, the demand for these will continue after the basic dosage form of the drug ceases to be in demand.

440. On the basis of the information available to the Director, there is no evidence that, when demand for a patented drug lessens, prices fall. Thus, in the comparative prices of broad-spectrum drugs set out above, it will be noted that prices of chlortetracycline and oxytetracycline are identical with those of tetracycline, a newer drug which has made heavy inroads on the sales of the first two. Also, it should be noted that the prices of the specialty products have remained unchanged. The situation which brings the price of a drug down is the drug becoming available to manufacturers generally, including those whose products are widely accepted by doctors. Once a drug becomes available to all manufacturers, prices drop. Conversely, until it does and regardless of a lessening of demand, prices tend to remain unchanged. In a few instances, spectacular reductions in the costs of production have been achieved and prices have been reduced as a result. But these instances are not necessarily exceptions

to the previous statement because even the new prices are usually high in relation to the reduced costs of production. [Note: Towards the end of 1960, reductions in the prices of certain drugs were made by some manufacturers. Complete details were not known when this was written, but will be obtained and made available to the Commission. It is not believed that these price reductions affect the correctness of the conclusions suggested in this paragraph.]

441. The dominance of branches and subsidiaries of United States drug firms and the widespread use in Canada of drug products originated in the United States mean that the drug trade in Canada in effect operates under the United States patent system. Products are patented in the United States and their prices set on the basis that the patent holders have a legal monopoly on the sale of these products. Corresponding Canadian patents are then obtained and the drug is supplied to the Canadian market (either directly or through a Canadian subsidiary) at at least as high a price as that charged in the United States. If the price is in fact the same, then the Canadian consumer will pay this price plus sales tax.

442. The question of patents and the special provisions of the Canadian Patent Act relating to compulsory licences in the case of patents on food and drugs raise broad issues and it is emphasized that nothing contained in this Statement is intended as a comment on these issues. The situation is that Canadian law provides for compulsory licences under patents relating to drugs, and the terms of the statute and the interpretation of these terms by the courts make it clear that the purpose of Parliament was to ensure that drugs would be available to the public at the lowest possible prices consistent with due reward to the discoverer of any particular drug. In effect, the exclusive monopoly normally conferred by a patent is modified in the case of a patent relating to a drug. However, in practice, the special provisions of the Patent Act have remained largely unused and monopoly control, through patents, is exercised over the manufacture, distribution and sale of certain drugs in Canada. This monopoly control is related to the situation in the United States where no similar provisions relating to compulsory licensing exist. The patent control exercised by manufacturers in that country, quite properly under

its laws, is extended to Canada because no other manufacturers have taken advantage of the special provisions of the Canadian law. The Canadian public pays prices which are set by manufacturers operating under the patent laws of the United States. In many cases, the Canadian price simply reflects the price originally set in the United States. In other cases, where a manufacturer from another foreign country besides the United States enters the Canadian market, the price which such manufacturer charges reflects the level of prices for patented products prevailing in this market.

Distribution of Drugs, and Markups and
Prices at the Retail Level

443. The price of drugs to the consumer depends on the price charged by the manufacturer to trade buyers and on the markup taken by trade buyers when the drugs are resold to consumers. It is obvious that the general level of prices depends on the prices charged by the manufacturers. Competition at the retail level will influence the price paid by the consumer, but only within limits. No degree of competition is likely to result in a product for which a manufacturer charges the retailer one dollar being resold at the same price as a product for which the manufacturer charges the retailer five dollars. Nevertheless, the markup taken by the retailer is an important factor in determining the selling price to the consumer.

444. Actually, according to the practice in the trade, prices to trade buyers are almost always determined by applying discounts to the list or suggested resale prices fixed by the manufacturer. A manufacturer normally issues catalogues and price lists which show the list prices and then announces the discounts which it will allow. Price lists showing actual net prices to hospitals are frequently issued because the computation of net prices from list prices, involving the deletion of sales tax as well as discounts, is complicated and because special prices may be charged hospitals on certain products. Subject to this exception, most price lists show the list price and this appears to have the effect of establishing such price as "the price" of the particular product. Thus, if the list price of a product is, for example, one dollar, that is likely to be regarded as the correct selling price of that product regardless of whether the

retailer has purchased from a wholesaler at perhaps seventy cents, direct from a manufacturer at sixty cents, or even on a purchase under a special deal at fifty cents. As already noted, the Canadian Pharmaceutical Journal publishes a price book (which is revised every six months) showing the manufacturer's list price for virtually every product sold by drug stores. The use of this book undoubtedly tends to reinforce the practice of treating the list or suggested resale price as the correct selling price.

445. Drugs are sold by manufacturers (or distributors at the manufacturers' level) both through wholesalers and direct to retail druggists and to hospitals. Discounts to wholesalers vary from firm to firm but a discount of 40 per cent and $16\frac{2}{3}$ per cent is probably the most common. This appears to be the largest discount normally allowed by any of the more important ethical drug firms. From this point, discounts range downward to about 40 per cent. Some manufacturers either refuse to sell direct to retail druggists or discourage such sales, but the great majority of manufacturers sell direct to retail druggists and almost invariably allow a 40 per cent discount on such sales. When a wholesaler which has received a discount of 40 per cent and $16\frac{2}{3}$ per cent from a manufacturer resells to a retailer, the wholesaler normally allows the retailer a discount of 40 per cent. If the wholesaler's own discount is less than 40 per cent and $16\frac{2}{3}$ per cent, the discount which it allows the retailer will be correspondingly less. As noted, certain small manufacturers allow larger discounts than those mentioned. A small manufacturer may publish the same list price for a particular product as a larger manufacturer but offer much larger trade discounts. If the list price is followed when the product is resold, this means that the consumer pays the same price but that the dealer makes a larger profit on the product of the small manufacturer. Another difference is that the small manufacturer frequently allows a larger discount to doctors, often the same discount given dealers. Most large firms allow a 25 per cent discount to doctors who are allowed to purchase direct and a 15 per cent discount on purchases by doctors through drug stores. Some of the implications of the different rates of discounts as they affect prices to hospitals are referred to below.

446. The information available to the Director indicates that there is competition among wholesalers but that it has little effect on ultimate selling prices. As already noted, the price at which a wholesaler sells to a retailer or a hospital is calculated by allowing a discount off the list or suggested resale price of the product. This discount is related to the discount the wholesaler itself receives from the manufacturer. The discounts allowed by wholesalers to retailers tend to be standard, i.e., different wholesalers allow the same discount on the same product. Competition takes the form of allowing year-end rebates, or paying part or all of the delivery charges, or the like. In Ontario, for example, Drug Trading Company Limited, a co-operative of retail druggists, allows its members a rebate and privately owned wholesale firms have been forced to adopt a similar practice to remain competitive. Regardless of what form competition takes, it rarely extends to offering a special price on a particular product except to pass on a special deal offered by a manufacturer (which, of course, would be available from all wholesalers). A retailer may, therefore, effect a general saving by buying from one wholesaler rather than another, but is unlikely to obtain better prices on a particular product. (The foregoing relates to drug products; the practice in respect to sundry items which are not drugs but are commonly sold in drug stores may be somewhat different.) As far as drug products are concerned, there appears to be no such thing as a retailer obtaining a special price from a wholesaler on a particular product which would allow the retailer to offer a special price to his customers.

447. Although retail druggists can usually purchase more advantageously by placing orders directly with a manufacturer, for various reasons which have been discussed they buy a large proportion of their requirements through wholesalers.

448. Hospitals do not normally pay sales tax on the drugs which they purchase. Generally, hospitals buy drugs on the same discount basis as a retailer but, because sales tax is also deducted, the actual price paid is about ten per cent below that paid by a retailer. This is so whether the purchase is made directly from a manufacturer or through a wholesaler.

449. While hospitals normally buy at ten per cent less than the retail

druggist, they frequently purchase on even more favourable terms because of special prices to hospitals on particular drugs. These have been illustrated above.

450. A further aspect of discounts and special prices to hospitals may be noted. The fact that certain small manufacturers allow larger trade discounts than those normally allowed by large manufacturers means that there is a different relationship between the trade prices and the list prices of the two classes of firms. To take hypothetical figures, if a large manufacturer's list price is \$10.00, its dealer price will normally be \$6.00 and its hospital price \$5.40. If a small firm's list price is \$10.00, its dealer price may be \$5.00 and its price to hospitals \$4.00. However, these prices are usually the lowest offered in any circumstances, while the large firm may quote a special hospital price of, again taking a hypothetical figure, \$3.00. Thus, even where list prices are the same, prices to different trade buyers may be different. When list prices are not the same, the situation is even more complicated. It is essential, in comparing prices, to determine the class of customer to which prices are applicable and whether any special prices are in effect. This point is mentioned because, on occasion, comparative prices are published which are in some respects misleading.

451. The lower prices paid by hospitals are primarily due to the fact that a hospital is treated as a trade buyer which is allowed to buy directly from the manufacture or wholesaler. The situation is parallel to that in other fields where institutional accounts may purchase directly from manufacturers or wholesalers, but an individual consumer must buy at retail.* The differences in the drug field are greater because, quite apart from special prices to hospitals, hospitals do not pay sales tax and the individual consumer will, in many instances, have to pay a prescription fee. There is, too, the further difference that in other

*Presumably the practice of hospitals buying directly from the manufacturers is at least partly due to the fact that hospitals do not pay sales tax. Where the sale is made by the manufacturer, the goods are invoiced less sales tax and that is the end of the matter. If the hospital purchases from a wholesaler, the wholesaler will have already paid the sales tax and must make application for a refund. It is understood that in the United States, where there is no Federal sales tax on drugs, hospitals usually purchase through wholesalers.

fields only purely commercial considerations are involved. In the drug field, the sale of certain drugs to consumers only through drug stores under the supervision of properly qualified pharmacists is part of the control exercised over the sale and distribution of drugs.

452. Special hospital prices are, in some instances, much lower than regular trade prices. Presumably a manufacturer receives a smaller net return on sales made at these prices. Presumably, too, the fact that very low prices are charged hospitals is some indication of the cost of preparing the drugs to which these prices apply and also that sales at regular prices (depending on such factors as volume of sales, etc.) are quite profitable to the manufacturer.

453. The discounts allowed by manufacturers on proprietary drugs appear to be, on the average, somewhat smaller than those allowed on ethical drug products.

454. No attempt has been made in the Statement to set out all the details relating to quantity discounts allowed on large purchases or of "deals" which are offered from time to time by most manufacturers. Such deals appear to be much more frequently offered in connection with sales of proprietary drugs and the commoner ethical drug products.

455. The discount structure and the fact that public hospitals do not pay sales tax on drugs mean there are wide differences in the prices paid by hospitals and the prices paid by persons purchasing from a drug store. For most ethical drugs, without considering special low hospital prices, the hospital pays 10 per cent less than a retail druggist, i.e., it buys at about 54 per cent of list price, whereas the purchaser in a drug store pays list price and, if the drug is purchased on prescription, a prescription fee in addition. If a special price is allowed the hospital, the price paid by a purchaser in a drug store may be several times the hospital price. The difference in price is frequently increased because of other factors, such as the purchaser in a drug store having to buy in small, relatively more expensive packages, in more expensive dosage forms, or the like.

456. As noted, the retail druggist's markup is 40 per cent of selling price or $66\frac{2}{3}$ per cent of cost price when he buys at a discount of 40 per cent. This will normally be the case if he buys direct from the

manufacturer. However, while the situation will vary from retailer to retailer, it appears clear that the bulk of the drugs sold by retail druggists are purchased through wholesalers and that the discounts which the retail druggists receive probably average below 40 per cent. Obviously, there will be a considerable difference in the position of a chain of drug stores as compared with a single drug store; the former can presumably take advantage of special quantity prices, for example. Similarly, an Ontario druggist who receives a rebate on his purchases from Drug Trading Company Limited is in a more favourable position than a druggist elsewhere who receives no such rebate.

457. In assessing price competition at the retail level, a distinction must be drawn between different types of drug products. Certain common proprietary drugs are sold both in drug stores and in other outlets. Such products as Bayer's Aspirin or Bromo-Seltzer, for example, are usually on sale at every small corner store. Department stores frequently have a "drug sundry" counter at which a variety of proprietary drug products are sold. It is impossible to make any general statement about the selling prices of the proprietary drug products sold in this way because of the variety of outlets involved.

458. Other proprietary products are usually sold only by drug stores. This may be due to the fact that the product is not of a type suitable for merchandising through non-drug store outlets or it may be due to the fact that the manufacturer, as a matter of policy, sells only to drug stores. Many manufacturers of ethical drug products, which also manufacture proprietary drug products, only sell the latter through drug stores. No exhaustive survey of resale prices charged by drug stores for proprietary products was made during this inquiry. A survey of the Montreal area was carried out some years ago as part of the Loss-Leader inquiry. The results are set out in Chapter VII of the volume of material collected by the Director for the purposes of that inquiry (published by the Department of Justice, 1954). The material shows that there was some price cutting on proprietary drug products. This probably continues to be the case, although such price cutting is not widespread and most druggists appear to observe manufacturers' suggested resale prices as a matter of course. From comment

in trade journals and similar information, the chief complaint by druggists about price cutting on this class of products relates to the operation of discount houses. As will be noted below, there are a few discount drug stores and these stores cut prices on proprietary and sundry products as well as on ethical drugs. However, the discount houses referred to here are ones such as Lord's Super Value Stores (in Toronto and a few other Ontario cities). These firms are not drug stores and cannot handle ethical drugs, but do carry many lines of proprietary and sundry products. The firm named seems to be the most important firm of this type, although there are others. As a group, retail druggists are strongly opposed to price competition at the retail level but, whatever special considerations may arise in relation to sales of ethical drugs, it is difficult to understand why there should not be normal price competition in the retail sale of proprietary and sundry drug products.

459. Ethical drug products may only be sold through drug stores. There are also, as already noted, certain other products which manufacturers, by choice, sell only through drug stores. The vitamin lines of the ethical drug manufacturers are examples. The only significant difference between drugs which must be sold through drug stores and those which are sold through drug stores as a matter of choice is that the latter may be advertised directly to the public. Otherwise, any comment on "over the counter" ethical drug products applies to both.

460. Discount drug stores are rare in Canada. Englander's located in Honest Ed's in Toronto and Pay-N-Save Drugs in Winnipeg, Calgary and Edmonton appear to be the chief examples. Even these outlets can only advertise in general terms and cannot advertise specific ethical drug products directly to the public.

461. The restriction on advertising of ethical drugs (which is clearly necessary to prevent people treating themselves for serious conditions or diseases on the basis of statements made in advertisements) undoubtedly contributes to the lack of price competition. But the real force which prevents price competition at the retail level is the attitude of druggists and the moral pressure exerted by their associations. The list or suggested resale price set by the manufacturer is accepted as the correct and proper

selling price and is followed as a matter of course by most druggists. Failure by a druggist to observe these accepted prices is frowned on as chiselling and as verging on unethical conduct.

462. It does not appear that pressure to maintain retail prices is exerted by the manufacturers. Rather, if the experience of Mr. Englander (whose oral evidence will be before the Commission) is an accurate indication of conditions, it is the retailers who exert pressure on the manufacturers and wholesalers. In any event, despite the fact that resale price maintenance is not enforced, the setting of list prices by the manufacturers and the acceptance of these prices throughout the trade produce exactly the same result. Subject to very minor exceptions, a purchaser of an ethical drug product in a drug store will pay the manufacturer's suggested resale price and will be unable to obtain the product more cheaply by shopping around.

463. It has been pointed out above that in those States in the United States where resale price maintenance is legal and is enforced under the so-called Fair Trade laws, the minimum resale price is usually somewhat below the full list price. In Canada, the practice is to charge the full list price although, of course, there is no legal requirement that this be done. There is that further factor that in Canada the number of alternative products of any given type is usually relatively small. In the United States, for any product which is not controlled by patents, there are usually numerous alternative brands available and the consumer has a much wider choice at a wider range of prices.

464. The pricing of prescriptions has been discussed at some length in the Statement. It is clear that most druggists follow schedules of suggested prices prepared by either local or Provincial associations (except in British Columbia where the schedule is published by a private firm). These schedules do not, in most instances at least, appear to embody formal agreements, although this aspect has not been tested under the Combines Investigation Act. Very occasionally, individual druggists will depart from the applicable schedule and most apparently feel free to do so even if they do not actually do so in practice. The only drug stores which are known to offer prescriptions at special prices on a regular basis

are Englander's in Toronto and Ellerby & Hall in Winnipeg. It may be noted in passing that pharmacists are urged to use a code to mark the price which they have charged on a prescription so that, if it is refilled by another pharmacist, the same price can be charged.

465. Pharmacists take the view that the status of their profession would be demeaned and that the standard of professional service to the public would suffer if price cutting on ethical drug products, and especially on prescriptions, should become widespread. These and similar aspects require careful consideration. However, the situation which presently exists appears to raise questions of the propriety of druggists' associations performing the dual roles of regulating the profession of pharmacy and the operation of drug stores from the point of view of protecting the health of the public and controlling the distribution of narcotic and other potentially dangerous drugs on the one hand, and acting as trade associations concerned with the economic welfare of their members as retail merchants on the other hand. There is obviously a danger of a conflict of interest between the two roles. Further, even if it is admitted that it is proper for the pharmacist to charge a fee, which is added to the regular resale price of the product, for filling a prescription, it may be questioned if the amount of such fee should be determined solely by the pharmacist. If the consumer is to be denied the protection normally afforded by price competition among his suppliers, it would seem desirable that some other means of protecting his interest should be found. It should be emphasized that no objection is taken to the pharmacist charging an adequate professional fee as remuneration for the exercise of his professional skill and the responsibility he takes in filling the prescription issued by a doctor. It does, however, appear relevant to observe that the pharmacist's remuneration for his professional services should be clearly distinguished from the markup that he takes on the resale of a product as a mere retailer of goods. It appears to the Director that there is confusion between the remuneration that he receives as a mere retailer of goods and that which he receives in his professional capacity which has led to the attitude that price cutting as a function of mere retailing is unethical in a professional sense. There has been general acceptance of the maintenance of the level of fees in the professions, but maintenance of resale prices has, as a general principle, been condemned by legislation.

CHAPTER XVIII

CONCLUSIONS

466. This has been a general inquiry under section 42 of the Combines Investigation Act. The inquiry is concerned with conditions or practices in the drug field which are related to monopolistic situations or restraint of trade but, for the purpose of determining the existence and effect of such conditions or practices, it has been necessary to examine conditions and practices in the drug field generally. As will be apparent from the Statement, certain conditions and practices have given rise to a great deal of controversy, and judgments about them will necessarily involve opinion. Oral evidence about such matters was not called by the Director. It was assumed that interested parties will wish to make submissions before the Commission so that any oral evidence taken by the Director would probably be repeated in any event and would involve a duplication of effort. Moreover, since proceedings before the Director necessarily involve the selection of witnesses and the gathering of evidence which he thinks relevant, and since those interested would undoubtedly wish to select their own spokesmen and present the evidence which they thought relevant, it was felt that hearings before the Commission would be a much more appropriate forum. The Statement has therefore been prepared in the expectation that representations on various points will be made to the Commission and the material set out represents an attempt to provide background and general information against which submissions on contentious points may be considered by the Commission.

467. The information obtained in this inquiry appears to indicate that, at the manufacturers' level, prices of certain drugs are affected by the control over the manufacture, distribution and sale of such drugs exercised through patents. The provisions of the Patent Act relating to compulsory licences appear to have proved ineffectual to combat this situation and the clear intent of the Act has been frustrated. This conclusion is not intended to imply any opinion about patents as such, it is intended simply to indicate that, in relation to the sale of drugs in Canada, patents have been and are being used to create monopolistic situations which the Canadian law appears to have been designed to prevent. The control exercised over the manufacture, distribution and sale of certain drugs through patents has

virtually eliminated price competition in respect of such drugs and has encouraged other forms of competition which, while possibly bringing other benefits to the public, have resulted in prices being increased rather than decreased. Practices which are quite legal and unobjectionable in themselves (promotion, use of trade names, and the like) appear to have been carried to extremes because of the insulation of certain sectors of the industry from price competition by reason of the control exercised through patents.

468. As is indicated below, the effects of the control exercised through patents affect the prices of certain drugs only. On the other hand, the practices of retail druggists which have been described and are also referred to below, affect the prices of all products sold in drug stores. These practices have resulted in the virtual elimination of price competition at the retail level.

469. Prices of drugs in Canada are among the highest in the world. These prices tend to reflect current prices of the same or comparative drug products in the United States but, because of the sales tax applicable in Canada, prices to consumers in Canada are about eleven per cent higher.

470. Drugs may be classified in several ways and, for certain types, while prices may be high in relation to prices in other parts of the world, these prices appear to be simply a reflection of general high costs in the Canadian and United States economies. In the case of new patent-controlled drugs, prices are high in the sense that a large markup over the cost of producing the drug is taken by the manufacturer. It is in respect of these drugs and to a lesser extent of trade-named specialties of the leading ethical drug houses that any question of prices being exorbitant arises.

471. During this inquiry, no detailed information was obtained about proprietary drugs, but general information indicates that prices of proprietary drug products are not unduly high in any sense. As in other fields, an established brand which has won wide public acceptance is normally sold at a premium price. However, there are usually numerous substitutes available and the consumer has a wide choice of products at various prices. It is obvious that, because considerations of health and

personal well-being are involved, brand and product preference is likely to be more important, even in the case of proprietary drug products, than in the case of other merchandise.

472. In the case of standard, widely available ethical drugs, the situation is much the same. Brand preference is probably somewhat more important and products of long-established ethical drug firms which enjoy a high reputation for the quality of their products are able to command premium prices. However, there are practical limits to the amount of the premium which can be charged. The history of the industry indicates that, once a drug becomes generally available to manufacturers (whose products are accepted by doctors) and numerous alternative products are offered, prices tend to fall until they reflect only a modest markup over actual cost of production. Moreover, as a drug becomes widely available, manufacturers usually stop promoting it aggressively and concentrate on promoting their more exclusive lines. This undoubtedly reduces general costs of sale and distribution of the particular drug.

473. Various reasons are advanced for the higher prices of new patent-controlled drugs and these have been discussed in the Statement. Regardless of what conclusions may be reached in respect of such matters, the fact which makes high prices possible is the patent control exercised over such drugs.

474. The clear intention of the special provisions of the Canadian patent law is that this situation should not obtain. However, advantage has not been taken of these provisions and the drug industry in Canada is, for all practical purposes, operating under conditions determined by the patent law of the United States.

475. Patent-controlled drugs are imported into Canada by a few small firms from foreign sources and without licence arrangements with the Canadian patent holders. Because a number of actions arising out of this practice are before the courts, it has not been thought proper to make any detailed comment or express any opinion on this situation. The basic facts are that such importations are made and that the importing firms offer dosage forms of such drugs at lower prices than the equivalent products offered by the patent holders.

476. To date, the availability of such products does not appear to have had any significant effect on the prices charged by the firm holding patents except to a very limited extent in the case of some institutional buyers. This is due to a controversy which has raged and continues to rage about the quality of the imported products and the products of small firms. Unless and until doctors generally are satisfied as to the quality of such products, their impact on the market and on the prices of established brand-named products will continue to be slight. The situation would be entirely different if such drugs were available to all manufacturers. It will be understood, of course, that the foregoing is not intended as an expression of opinion either about the propriety of such importations or about the actual quality of such drugs. As has been noted, revisions to the regulations dealing with the inspection of drug products are now under consideration. These revisions, when made, will undoubtedly affect the acceptance of the products of various manufacturers and importers.

477. The foregoing is related to the question whether doctors should prescribe drugs by generic names rather than brand names. Undoubtedly, the adoption of this practice (to the extent that it is practical) would exert some pressure on the prices of brand-named products. However, as explained in the Statement, this question is much more complicated than appears at first glance.

478. From the manufacturers' level, drugs move either directly or through wholesalers to hospitals, and either directly or through wholesalers to retailers for resale to the public.

479. Hospitals buy drugs on special terms because they do not pay sales tax, frequently buy in larger quantities and, in respect of certain products, are charged lower prices than other trade buyers. Because hospitals buy either direct from the manufacturer or through a wholesaler, they are not affected by practices at the retail level.

480. There is very little price competition at the retail level and that which does exist is chiefly on proprietary and sundry drug products. Apart from a very few discount drug outlets, most drug stores sell ethical drug products at the manufacturers' suggested resale prices as a matter of course. This appears to be due firstly to the practice of the manufacturers in basing all trade prices on the list or suggested resale price and the

acceptance of this price as the only proper selling price; and, secondly, to the pressure exerted by pharmacists' associations on their members to maintain prices.

481. In most Provinces, schedules of suggested prices to be charged for drugs supplied on prescription have been prepared by the Provincial pharmacists' associations. Apparently, the Canadian Pharmaceutical Association is working toward a uniform scale of prices of prescriptions for the whole of Canada. It is not known to what extent the present suggested schedules are followed in the different Provinces, but reports at annual meetings of Provincial groups indicate widespread acceptance and use. These schedules clearly have the support of the official organizations of druggists and this probably contributes to their acceptance. Regardless of whether or not they follow the schedules, most druggists appear to frown on price competition in the pricing of prescriptions and to regard such competition as at least verging on unethical professional conduct.

482. No attempt has been made in this Statement to appraise the reasonableness of the markup taken by retail druggists, nor to assess the propriety of including a prescription fee in the price of drugs sold on prescription. A consideration of these matters would involve a detailed study of the retail drug trade and of broad questions as to the control of the distribution of drugs and narcotics in relation to public health. On the latter aspect, it is obvious that cost is only one consideration.

483. Without expressing any opinion on these matters, it may be noted that the retail markup taken on all drugs and the additional prescription fee included in the resale price of drugs sold on prescription, accounts for a substantial part of the final price paid by the consumer. It is not possible to state whether these markups or prescription fees are too high in an absolute sense. It is, however, clear that there is virtually no price competition in the sale of ethical drug products at the retail level. Price competition among suppliers is the factor which is normally relied upon to control the prices charged by suppliers and to ensure that consumers can purchase at reasonable prices. In

the case of ethical drugs, no such control exists.

Dated at Ottawa in the Province of Ontario this 28th day of
February, 1961.

(Sgd.) "D. H. W. Henry"
.....
D. H. W. Henry
Director of Investigation and Research

APPENDIX I

PARTIAL LIST OF FIRMS MANUFACTURING OR DISTRIBUTING DRUGS SHOWING (1) FIRMS WHICH ARE SUBSIDIARIES OF OR ARE RELATED TO FOREIGN COMPANIES AND (2) FIRMS WHICH ARE DISTRIBUTORS OF PRODUCTS OF FOREIGN COMPANIES

Notes:

1. This is not a complete list of drug firms in Canada.
2. Since the Statement refers to statistics published by the Dominion Bureau of Statistics, the list shows all firms which reported to DBS in the last year for which this information is available. The notation "DBS" in brackets appears after the name of each such firm.
3. Because all firms reporting to DBS are shown, the list necessarily includes some very small firms and also, as appears from the DBS Report, firms in the veterinary medicine field and other related fields.
4. It is believed that the list includes all large ethical drug firms as well as a substantial number of the smaller firms.
5. Wholesale drug firms, as such, are not listed, but the names of some are included because they are shown in the DBS Report or because they are distributors for foreign companies.
6. A widely-used list of drug firms and distributors is given in Drug Index (published as a supplement to the trade magazine, Drug Merchandising). Where a firm shown in this appendix is listed in Drug Index, the notation "DI" in brackets appears after the name. Not all firms listed in Drug Index are shown in this Appendix.
7. Where a firm is a member of the Canadian Pharmaceutical Manufacturers Association, the notation "CPMA" in brackets appears after the name. Generally, this means that the firm is important in the industry.
8. Information about the relationship between specific Canadian and foreign companies was obtained from various sources. In some cases, the information was obtained directly, but in others it has been necessary to rely on secondary sources. No attempt has been made to give technical details of the exact relationship between particular companies.
9. For convenience, such words as "Company", "Canada", "Limited", and the like, have been abbreviated throughout.
10. Where a particular firm uses a French and an English name, the name shown by DBS has been used.
11. An asterisk before the name of a firm indicates that that firm was requested to supply information.

Canadian Firm

Foreign Firm

* Abbott Laboratories Ltd.,
Montreal, P.Q.
(DBS - DI - CPMA)

Abbott Laboratories,
Chicago, Illinois,
U.S.A.

Accurate Laboratories,
London, Ontario.
(DBS)

* Accurate Mfg. Chemists Inc.,
Montreal, P.Q.
(DBS - DI)

Adams Pharmacal Co. Ltd.,
Vancouver, British Columbia.
(DI)

Adanac Medical Supplies Reg'd,
Montreal, P.Q.
(DI)

Alcon Laboratories,
Don Mills, Ontario.
(DI)

Alcon Laboratories Inc.,
Fort Worth, Texas,
U.S.A.

Allied Veterinary Products Ltd.,
Kingston, Ontario, and
Winnipeg, Manitoba.
(DBS)

* Ames Co. of Can. Ltd.,
Toronto, Ontario.
(DI - CPMA)

Ames Co. Inc.,
Elkhart, Indiana,
U.S.A.

* Anca Pharmaceutical Div.,
The Wander Co. of Can. Ltd.,
Oshawa, Ontario.
(Formerly Anglo-Canadian Drug Co.)
(DBS - DI - CPMA)

The Wander Co.,
Chicago, Illinois,
U.S.A.

Anchor Serum Co. of Can.,
Toronto, Ontario.
(DI)
(Veterinary products)

Anchor Serum Co.,
St. Joseph, Missouri,
U.S.A.

Andal Laboratories Ltd.,
St. Romuald, P.Q.
(DBS - DI)

J. H. Andrews Ltd.,
Verdun, P.Q.
(DI)
Distributor for -

W. F. Young Inc.,
Springfield, Massachusetts,
U.S.A.

* Anglo-French Drug Co. Ltd.,
Montreal, P.Q.
(DBS - DI - CPMA)
Distributor for -
Roussel (Can.) Ltd.

Roussel Laboratories Ltd.,
London, England.

Les Laboratoires Roussel,
Paris, France.

Le Laboratoire du Bacteriophage,
Paris, France.

(cont'd)

Canadian Firm

Foreign Firm

* Anglo-French Drug Co. Ltd. (cont'd)

British-Felsol Co. Ltd.
London, England.

Les Laboratoires Robert & Carrière,
Paris, France.

Hobart Laboratories, Inc.,
Chicago, Illinois,
U.S.A.

Pharmaceutische Fabriek Roter,
Hilversum, Holland.

Walker Laboratories Inc.,
Mount Vernon, New York,
U.S.A.

The Arex Co. Enrg.,
Lauzon, P.Q.
(DBS - DI)

* Arlington-Funk Laboratories Div.,
U.S. Vitamin Corp. of Can. Ltd.,
Montreal, P.Q.
(DI - CPMA)

U.S. Vitamin & Pharmaceutical Corp.,
New York, New York,
U.S.A.

Arrow Laboratories,
Montreal, P.Q.
(DI)

* Astra Pharmaceuticals (Can.) Ltd.,
Toronto, Ontario.
(DBS - DI - CPMA)

AB Astra,
Sodertalje, Sweden.

* Atlantic Trading Co.,
Toronto, Ontario.
Distributor for -

Marsing & Co., Denmark, and other
European firms.

* Austin Laboratories,
Guelph, Ontario.
(DBS - DI)
Distributor for -

Chatham Pharmaceuticals Inc.,
Newark, New Jersey,
U.S.A.

Eaton Laboratories,
Norwich, New York,
U.S.A.

* Ayerst, McKenna & Harrison Ltd.,
St. Laurent, P.Q.
(DBS - DI - CPMA)

American Home Products Corp.,
New York, New York,
U.S.A.

The Baird Co. Ltd.,
Woodstock, New Brunswick.
(DBS - DI)

Bauer & Black Div.,
The Kendall Co. Ltd.,
Toronto, Ontario.
(DI)

Bauer & Black,
Chicago, Illinois,
U.S.A.

* Baxter Laboratories of Can. Ltd.,
Alliston, Ontario.
(DBS - DI - CPMA)

Baxter Laboratories Inc.,
Morton Grove, Illinois,
U.S.A.

The Bayer Co.
(See Sterling Drug Mfg. Co. Ltd.)

Canadian Firm

Beck Bros. & Turner Ltd.,
Montreal, P.Q.
(DI)

Distributor for -

Milton Sales (Can.) Ltd.,
Montreal, P.Q.

* Beecham Research Laboratories Ltd.,
also Beecham Products Ltd.,
Weston, Ontario.

(DBS - DI - CPMA)

* (Formerly Harold F. Ritchie & Co.
Ltd. and so listed by DBS)

* Bell-Craig Ltd.,
Toronto, Ontario.
(DBS - DI)

* Frank L. Benedict & Co. Ltd.,
St. Laurent, P.Q.
(DI)

Distributor for -

Better Proprietaries Ltd.,
(Can-Wide Distributors Ltd.)
Toronto, Ontario. (DI)
Distributor for -

Foreign Firm

Dr. B. J. Kendall Co.,
Griswoldville, Massachusetts,
U.S.A.

E. F. Longdale Ltd.,
Surrey, England.

W. J. Rendell Ltd.,
Herefordshire, England.

Resinol Chemical Co.,
Baltimore, Maryland,
U.S.A.

Sharland & Co. (London) Ltd.,
London, England.

Beecham Group Ltd.,
London, England.

Chivers Ltd.,
England.

Natcon Chemical Co. Inc.,
Bethpage, New York,
U.S.A.

Aveeno Corp.,
New York, New York,
U.S.A.

Chap Stick Co.,
Lynchburg, Virginia,
U.S.A.

The Grove Laboratories Inc.,
St. Louis, Missouri,
U.S.A.

H. A. Hampshire Co.,
Derby, England.

Horlicks Corp.,
Racine, Wisconsin,
U.S.A.

Sergeants Dog Care Products
(Polk Miller Products Corp.),
Richmond, Virginia,
U.S.A.

York Drug Co. Inc.,
New York, New York,
U.S.A.

Canadian Firm

Foreign Firm

* Bio-Chemical Laboratory Inc.,
Montreal, P.Q.
(DI)

Biochemia Co. Reg'd,
Montreal, P.Q.
Distributor for -
The Royal Jelly Co. Reg'd.

Bonzoe Products,
Winnipeg, Manitoba.
(DBS)

* Brent Laboratories Ltd.,
Toronto, Ontario.
(DBS - DI)
Distributor for -

Drobena Drug Manufacturer,
Berlin Stelitz, Germany.

Forchungs Laboratory,
Berlin Dahles, Germany.

Arnar-Stone Laboratories Inc.,
Mount Prospect, Illinois,
U.S.A.

Standard Pharmaceutical Co. Inc.,
New York, New York,
U.S.A.

* Bristol Laboratories of Can. Ltd.,
Montreal, P.Q.
(DBS - DI - CPMA)

Bristol-Myers Co.,
New York, New York,
U.S.A.

Bristol-Myers Co. of Can. Ltd.,
Toronto, Ontario.
(DI)

Bristol-Myers Co.,
New York, New York,
U.S.A.

* The British Drug Houses (Can.) Ltd.,
Toronto, Ontario.
(DBS - DI - CPMA)

The British Drug Houses Ltd.,
London, England.

W. K. Buckley Ltd.,
Toronto, Ontario.
(DBS - DI)

W. K. Buckley Inc.,
Buffalo, New York,
U.S.A.

* Burroughs Wellcome & Co. (Can.) Ltd.,
Ville La Salle, P.Q.
(DBS - DI - CPMA)

The Wellcome Foundation Ltd.,
London, England.

* Calmic Ltd.,
Toronto, Ontario.
(DI)

Calmic Ltd.,
Crewe, England.

* Canada Drug Ltée,
Montreal, P.Q.
(DBS - DI)

* Canada Pharmacal Co. Ltd.,
London, Ontario.
(DBS - DI)

* Carter, Cummings & Co. Ltd.,
Aurora, Ontario.
(DBS - DI - CPMA)

Sterling Drug Inc.,
New York, New York,
U.S.A.

Canadian Firm

Foreign Firm

N.S. Carter Products Ltd.,
(Wallace Laboratories),
Toronto, Ontario.
(DI)

Carter Products Inc.,
New York, New York,
U.S.A.
(Wallace Laboratories Inc., New
Brunswick, New Jersey, is the ethical
drug division.)

* Casgrain & Charbonneau Ltd.,
Montreal, P.Q.
(DBS - DI - CPMA)

Dr. A. W. Chase Medicine Co. Ltd.,
Oakville, Ontario.
(DBS - DI)

Cheivers Foods Ltd.,
St. John's, Newfoundland,
(DBS)

* Christiaens Pharmaceutical (Can.) Ltd.,
Montreal, P.Q.
(DI)

Manufacture de Produits Pharmaceutique
A. Christiaens S.A.,
Brussels, Belgium.

* Ciba Co. Ltd.,
Montreal, P.Q.
(DBS - DI - CPMA)
(See also Mount Royal Chemicals Ltd.)
Cie des Produits Biologiques Europa
Ltd.,
Montreal, P.Q.
(DBS)

Ciba Ltd.,
Basle, Switzerland.

Cie des Produits Homah Inc.,
(Homah Products Co. Inc.)
Montreal, P.Q.
(DBS - DI)

Cie Mathieu Ltée,
Sherbrooke, P.Q.
(DBS - DI)

La Cie Paula Ltée,
Montreal, P.Q.
(DBS - DI)

Cleveland's Drug Ltd.,
Toronto, Ontario.
(DBS - DI)

Compagnie Parmaco-Chemique Inc.,
Montreal, P.Q.
(DBS)

Compagnie Pharmed Ltée,
Montreal, P.Q.
(DBS)

W. H. Comstock Co. Ltd.,
Brockville, Ontario.
(DBS - DI)

* (N. C. Polson & Co. Ltd. is a
subsidiary)

* Connaught Medical Research Laboratories,
(University of Toronto).
(DBS - DI)

Canadian Firm

Co-operative Farex Ltée,
Montreal, P.Q.
(DBS - DI)
(This firm apparently acts as
distributor for a number of local
firms.)

* Corbin Pharmaceuticals,
Toronto, Ontario.
(DBS)

* Coronet Drug Co.,
Montreal, P.Q.
(DI)

* Corporation Pharmaceutique Francaise
Ltée,
Montreal, P.Q.
(DBS - DI)
Distributor for -

Foreign Firm

Distributor for the pharmaceutical
specialties of several French
manufacturers.

Laboratoires Baude,
Paris, France.

Biochimica, S.A.,
Zurich, Switzerland.

Laboratoires Bréant,
Paris, France.

Union de Pharmacologie Scientifique
Appliquée (U.P.S.A.),
Paris, France.

Laboratoires Couturieux,
Paris, France.

Laboratoires Despruneaux,
Fontenay-sous-Bois, France.

Laboratoires Fraysse,
Nanterre, France.

Laboratoires Laleuf,
Paris, France

L.A.P.R.A.,
Toulouse, France.

Laboratoire de Recherches Thérapeutiques,
Paris, France.

Laboratoires Porcher,
Paris, France.

Laboratoires Jean Olive,
Paris, France.

Laboratoires Robin,
Antony, France.

Laboratoires Savoie,
Vendome, France.

Wynlit Pharmaceuticals,
Zurich, Switzerland.

Allcock Products Ltd.,
Liverpool, England.

Canadian Firm

* Crookes-Barnes Can. Ltd.,
Ste. Therese de Blainville, P.Q.
(DI)

* Charles C. Cummings & Co.,
Toronto, Ontario.
(DBS - DI)

* Cyanamid of Can. Ltd.,
Montreal, P.Q.
(DBS - DI - CPMA)

Daillac Ltée,
Montreal, P.Q.
(DBS - DI)

Dairy Association Co.,
Rock Island, P.Q.
(DBS)

* Davis & Lawrence Co. (Can.) Ltd.,
Montreal, P.Q.
(DBS - DI)

* (Moore-Thompson-Clinger Ltd.,
Hamilton, Ontario, is a wholly-
owned subsidiary)

* Delmar Chemicals Ltd.,
Lachine, P.Q.
(DBS)

* Denver Chemical Mfg. Co.,
Town of Mount Royal, P.Q.
(DBS - DI)

* Desautels Laboratories Ltd.,
Montreal, P.Q.
(DBS - DI)

* Desbergers Ltd.,
Montreal, P.Q.
(DBS - DI)

* Dohow Chemical Co. Ltd.,
Montreal, P.Q.
(DBS - DI)

Dominion Chemical Laboratories,
Winnipeg, Manitoba.
(DBS)

Dodds Medicine Co. Ltd.,
Toronto, Ontario.
(DI)

Druggists' Corp. Ltd.,
Toronto, Ontario.
(DBS - DI)

* Dymond Drugs Ltd.,
Brantford, Ontario.
(DI)

The T. Eaton Drug Co. Ltd.,
Toronto, Ontario.
(DBS)

Foreign Firm

Chemway Corp. of Fairfield Road,
Wayne, New Jersey,
U.S.A.

American Cyanamid Co.,
New York, New York,
U.S.A.

Dairy Association Co. Inc.,
Lyndonville, Vermont,
U.S.A.

Davis & Lawrence Co.,
Dobbs Ferry, New York,
U.S.A.

Branch of Stamford, Connecticut,
U.S.A.

Doho Chemical Corp.,
New York, New York,
U.S.A.

Dodds Medicine Co. Inc. of U.S.,
Hamburg, New York,
U.S.A.

Canadian Firm

Foreign Firm

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| <p>✕ J. Eddé Ltée,
Montreal, P.Q.
(DI)</p> <p>✕ Elliott-Marion Co. Ltd.,
Montreal, P.Q.
(DI)</p> <p>Elmo Corn Salve,
Toronto, Ontario.
(DBS)</p> <p>✕ Endo Drugs (Can.) Ltd.,
Montreal, P.Q.
(DI)</p> <p>Esteye Co. of Can.,
Montreal, P.Q.
(DBS)</p> <p>Ex-Lax Ltd.,
Montreal, P.Q.
(DBS - DI)</p> <p>Dr. Peter Fahrney & Sons Co.,
Winnipeg, Manitoba.
(DBS)</p> <p>Familex Products Ltd.,
Montreal, P.Q.
(DBS - DI)</p> <p>✕ Fidelity Pharmaceutical Co. Ltd.,
Toronto, Ontario.
(DI)</p> <p>Controls -
Procol Mfg. Co. Ltd.,
Bowmanville, Ontario.
(DBS)</p> <p>and</p> <p>✕ H. Powell Chemical Co. Ltd.,
Bowmanville, Ontario.
(DBS - DI - CPMA)</p> <p>✕ Fine Chemicals of Can. Ltd.,
Toronto, Ontario.
(DBS)</p> <p>Fleming Bros. Ltd.,
Picton, Ontario
(DBS)</p> <p>Sapin Fortin,
Robertsonville, P.Q.
(DBS)</p> <p>Foster Dack Co. Ltd.,
Toronto, Ontario.
(DBS - DI)</p> <p>Frasier Thornton & Co. Ltd.,
Cookshire, P.Q.
(DBS - DI)</p> <p>✕ Charles E. Frosst & Co.,
Westmount, P.Q.
(DBS - DI - CPMA)</p> | <p>Endo Laboratories Inc.,
New York, New York,
U.S.A.</p> <p>Ex-Lax Inc.,
Brooklyn, New York,
U.S.A.</p> <p>Represents two American, one English
and one Dutch firm.</p> <p>S. B. Penick & Co.,
New York, New York,
U.S.A.</p> <p>Foster Dack Co.,
Chicago, Illinois,
U.S.A.</p> |
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Canadian Firm

Foreign Firm

Galt Chemical Products Ltd.,
Galt, Ontario.
(DBS)

* Gama Pharmaceuticals Ltd.,
Toronto, Ontario.
(DBS - DI)

* Geigy Pharmaceuticals Div.,
Geigy (Can.) Ltd.,
Montreal, P.Q.
(DI - CPMA)

* Gilbert & Co.,
Toronto, Ontario.
(DI)

Gilead Mfg. Co.,
Chilliwack, British Columbia.
(DBS)

* Glaxo-Allenburys (Can.) Ltd.,
* (Glaxo (Can.) Ltd.),
Weston, Ontario.
(DBS - DI - CPMA)

* E. C. Godwin & Associates,
Montreal, P.Q.
(Importer of bulk drugs)

A. N. R. Greens Ltd.,
Victoria, British Columbia.
(DBS)

C. C. Hanford Mfg. Co. Ltd.,
Brockville, Ontario.
(DBS - DI)

J. A. Harris Ltd.,
Montreal, P.Q.
(DBS - DI)

* The J. F. Hartz Co. Ltd.,
Toronto, Ontario.
(DBS - DI - CPMA)

Herbo Remedies Reg'd,
Montreal, P.Q.
(DBS)

* Herdt & Charton Inc.,
Montreal, P.Q.
(DI)

Hervay Remedies Ltd.,
St. Basile, P.Q.
(DBS - DI)

* Hoechst Pharmaceuticals of Can. Ltd.,
Montreal, P.Q.
(DI - CPMA)

J. R. Geigy S.A.,
Basle, Switzerland.

Glaxo Laboratories Ltd.,
Greenford, England.

G. C. Hanford Mfg. Co.,
Syracuse, New York,
U.S.A.

Distributor for a number of foreign
firms, chiefly French and American.

Farbwerke Hoechst AG,
Frankfurt, Germany,
and
The Upjohn Co.,
Kalamazoo, Michigan,
U.S.A.

Canadian Firm

Foreign Firm

* Hoffmann-La Roche Ltd.,
St. Laurent, P.Q.
(DBS - DI - CPMA)

F. Hoffmann-La Roche & Co. Ltd.,
Basle, Switzerland.

* Frank W. Horner Ltd.,
Town of Mount Royal, P.Q.
(DBS - DI - CPMA)

* A. H. Howard Chemical Co. Ltd.,
Orangeville. Ontario.
(DI)

* John A. Huston Co. Ltd.,
Toronto, Ontario.
(DI)

(The following are some of the firms which the company represents in Canada. Where both a Canadian and an American firm are shown opposite each other, these firms sell what appears to be the same product or products in Canada and the United States respectively, but details of the relationship, if any, between the two firms are not known.)

(Product, Berex Tablets (Ber-ex in U.S.))

* Berex Pharmacal Co. (DI)
(Operated by The Pan Pharmacals
Ltd.),
Toronto, Ontario.

Ives-Cameron Co. Inc.,
New York, New York,
U.S.A.

Dolcin Ltd.,
Toronto, Ontario.
(DI)

Dolcin Corp.,
New York, New York,
U.S.A.

* Homemakers Products (Can.) Ltd.,
Toronto, Ontario.
(DBS - DI)

Homemakers Products Div.,
George A. Breon & Co.,
New York, New York,
U.S.A.

E. Griffiths Hughes Ltd.,
Manchester, England.

Modern Products Inc.,
Milwaukee, Wisconsin,
U.S.A.

The Pan Pharmacals Ltd.,
Toronto, Ontario.
(DI)

Pan Pharmacals, Inc.,
New York, New York,
U.S.A.

Canadian Tampax Corp. Ltd.,
Toronto, Ontario.
(DI)

Tampax Inc.,
New York, New York,
U.S.A.

Westwood Pharmaceuticals,
Div. of Foster-Milburn Co.,
Buffalo, New York,
U.S.A.

* Ingram & Bell Ltd.,
Toronto, Ontario.
(DBS - DI - CPMA)

The Innerclean Co.,
Montreal, P.Q.
(DBS)

Canadian Firm

Foreign Firm

- * International Medicines Ltd.,
Montreal, P.Q.
(DI)

Inter Lab. Enrg.,
Laval, P.Q.
(DBS)
- * Intra Medical Products Ltd.,
Toronto, Ontario.
(DI)
- * C. E. Jamieson & Co. (Dominion) Ltd.,
Windsor, Ontario.
(DBS - DI)

Kent Chemicals Ltd.,
Vancouver, British Columbia.
(DBS)

Kogler Laboratories,
Waterloo, Ontario.
(DBS)

Laboratoire Bilophen Inc.,
Montreal, P.Q.
(DBS - DI)

Laboratoire Du. Cheptel Ltée,
Beloeil, P.Q.
(DBS)

Laboratoire Demers Ltée,
Montreal, P.Q.
(DBS - DI)
- * Laboratoire Lancet Ltée,
Montreal, P.Q.
(DBS - DI)

Les Laboratoire Laurence Enrg.,
Montreal, P.Q.
(DBS - DI)

Laboratoire Dr. Léo Lorrain Ltée,
Montreal, P.Q.
(DBS)

Laboratories Limited,
Vancouver, British Columbia.
(DBS)
- * Laboratoires Marois Ltée,
St. Eustache, P.Q.
(DI)

Laboratoire Montphar,
Montreal, P.Q.
(DBS - DI)
- * Laboratoire Nadeau Ltée,
Montreal, P.Q.
(DBS - DI - CPMA)
- * Laboratoire Octo Ltée,
Montreal, P.Q.
(DBS - DI)

Laboratoire Ortho Medico Enrg.,
Montreal, P.Q.
(DBS - DI)

Canadian Firm

Foreign Firm

Laboratoires St. Hubert Ltee,
Montreal, P.Q.
(DBS)

Laboratoire des Spécialités Pharmaceutiques et
Médicaments Brevetés Inc.,
Amos, P.Q.
(DBS)

Laboratoire Vincent Inc.,
Montreal, P.Q.
(DBS - DI)

x Lakeside Laboratories (Can.) Ltd.,
Toronto, Ontario.
(DI - CPMA)

Lakeside Laboratories Inc.,
Milwaukee, Wisconsin,
U.S.A.

Dr. J. O. Lambert Ltée,
Montreal, P.Q.
(DBS - DI)

x Laurentian - See National Drug &
Chemical Co.

Leeming Miles Pharmaceutical Inc.,
Montreal, P.Q.
(DBS - DI)

Lewis-Howe Co.,
Windsor, Ontario.
(DBS - DI)

Lewis-Howe Co.,
St. Louis, Missouri,
U.S.A.

A. Lilly,
St. John's, Newfoundland.
(DBS)

x Eli Lilly & Co. (Can.) Ltd.,
Toronto, Ontario.
(DBS - DI - CPMA)

Eli Lilly & Co.,
Indianapolis, Indiana,
U.S.A.

x Paul Lippens Inc.,
Montreal, P.Q.
(DBS - DI)

x Lloyd Bros. Pharmaceuticals,
Fort Erie, Ontario.
(DI - CPMA)

Lloyd Bros., Inc.,
Cincinnati, Ohio,
U.S.A.

Luscoe Products Ltd.,
Toronto, Ontario.
(DBS - DI)

x Lyster Chemicals Ltd.,
Montreal, P.Q.
(DI)

x Mallinckrodt Chemical Works Ltd.,
Montreal, P.Q.
(DBS - DI - CPMA)

Mallinckrodt Chemical Works,
St. Louis, Missouri,
U.S.A.

Maltby Bros. Ltd.,
Toronto, Ontario.
(DBS - DI)

x Paul Maney Laboratories (Can.) Ltd.,
Toronto, Ontario.
(DI)

Paul Maney Labs Inc.,
Cedar Rapids, Iowa,
U.S.A.

Canadian Firm

Foreign Firm

- G. W. Marlatt & Co.,
Willowdale, Ontario.
(DBS)
- x J. M. Marsan & Cie. Ltée,
Montreal, P.Q.
(DI)
- Marz Laboratories Ltd.,
Tecumseh, Ontario.
(DBS - DI)
- Matol Research Ltd.,
Quebec, P.Q.
(DBS)
- Earl H. Maynard Distributors,
Weston, Ontario.
(DI)
Distributor for -
- x McAlpine Pharmaceuticals Ltd.,
Toronto, Ontario.
(DBS)
- x McClung, Clemens Ltd.,
Toronto, Ontario.
(DI)
- x J. & R. McJannet Reg'd,
Montreal, P.Q.
(DI)
Distributor for -
- T. McMurdo Co. Ltd.,
St. John's, Newfoundland.
(DBS - DI)
- x Mead Johnson & Co. of Can. Ltd.,
Toronto, Ontario.
(DI - CPMA)
- The Mentholum Inter-American Inc.,
Fort Erie, Ontario.
(DBS - DI)
- x Merck & Co. Ltd.,
Montreal, P.Q.
(DBS - DI - CPMA)
- x The Wm. S. Merrell Co.,
St. Thomas, Ontario.
(DBS - DI - CPMA)
- Metro Drug Ltd.,
Montreal, P.Q.
(DBS - DI)
- The T. Milburn Co. Ltd.,
Toronto, Ontario.
(DBS - DI)
- x Miles Laboratories Ltd.,
Toronto, Ontario.
(DBS - DI)
- Cutter Laboratories,
Berkeley, California, U.S.A.,
and other firms.
- Seizfried Ltd.,
Zofingen, Switzerland.
- Mead Johnson & Co.,
Evansville, Indiana,
U.S.A.
- The Mentholum Co.,
Buffalo, New York,
U.S.A.
- Merck & Co. Inc.,
Rahway, New Jersey,
U.S.A.
- Vick Chemical Co.,
New York, New York,
U.S.A.
- Miles Laboratories Inc.,
Elkhart, Indiana,
U.S.A.

Canadian Firm

Foreign Firm

Minards Liniment Co. Ltd.,
Yarmouth, Nova Scotia.
(DBS - DI)
(Now owned by Beecham Products Ltd.)

x Moore - Thompson - Clinger Ltd.,
Hamilton, Ontario.
(DBS - DI)

Davis & Lawrence Co.,
Dobbs Ferry, New York,
U.S.A.

The Mothersill Remedy Co. Ltd.,
Montreal, P.Q.
(DBS)

x Mount Royal Chemicals Ltd.,
Dorval, P.Q.
(jointly owned by Ciba & Sandoz)

x Mowatt & Moore Ltd.,
Montreal, P.Q.
(DBS - DI - CPMA)

R. L. Mulveney's Remedies Ltd.,
Toronto, Ontario.
(DBS - DI)

National Drug & Chemical Co. Ltd.,
Montreal, P.Q. and elsewhere. (DI)
This firm is a very large drug whole-
saler. It operates two subsidiaries -

x Laurentian Laboratories Ltd.,
Montreal, P.Q.
(DBS - DI - CPMA)
which is a manufacturer and
packager of products largely for
sale through National Drug &
Chemical Co. Ltd. under "Nadruco"
and other labels,

and

x Laurentian Agencies Limited,
Montreal, P.Q.
(DI)
which acts as distributor for at
least thirty foreign and domestic
firms (only a few of which are
shown).

Armour Pharmaceutical Co.,
Kankakee, Illinois,
U.S.A.

Belmont Laboratories Co.,
Philadelphia, Pennsylvania,
U.S.A.

Coleman & Co. Ltd.,
Norwich, England.

McKesson & Robbins Inc.,
Bridgeport, Connecticut,
U.S.A.

National Drugs Ltd.,
(subsidiary of National Drug & Chemical
Co. Ltd.)
Winnipeg, Manitoba.
(DBS)

x Neo Drug Co.,
Montreal, P.Q.
(DI)

Nephron Agency of Can.,
Vancouver, British Columbia.
(DBS - DI)

Nephron Co.,
Tacoma, Washington,
U.S.A.

Canadian Firm

Foreign Firm

Nirvana Cie. Ltée,
St. Romuald, P.Q.
(DBS)

Nivea Pharmaceuticals Ltd.,
Town of Mount Royal, P.Q.
(DBS - DI)

Nixon Laboratories Ltd.,
Orangeville, Ontario.
(DBS - DI)

* Nordic Biochemicals Ltd.,
Montreal, P.Q.
(DBS - DI)

Northrop & Lyman Co. Ltd.,
Toronto, Ontario.
(DBS - DI)

* Norwich Pharmacal Co. Ltd.,
Toronto, Ontario.
(DBS - DI)

The Norwich Pharmacal Co.,
Norwich, New York,
U.S.A.

* Novocol Chemical Mfg. Co. of Can.
Ltd.,
Toronto, Ontario.
(DBS - DI)

Novocol Chemical Mfg. Co. Inc.,
Brooklyn, New York,
U.S.A.

Noxema Chemical Co. of Can. Ltd.,
Toronto, Ontario.
(DBS - DI)

Noxema Chemical Co.,
Baltimore, Maryland,
U.S.A.

Nu Life Pet Remedies Ltd.,
Vancouver, British Columbia.
(DBS)

* Organon Inc.,
Montreal, P.Q.
(DI)

N. V. Organon,
Oss, The Netherlands.

* Ortho Pharmaceuticals (Can.) Ltd.,
Toronto, Ontario.
(DBS - DI - CPMA)

Johnson & Johnson,
New Brunswick, New Jersey,
U.S.A.

C. Ottway Ltd.,
Toronto, Ontario.
(DBS)

Pacific Pharmaco Co. Ltd.,
Vancouver, British Columbia.
(DBS - DI)

* Parke, Davis & Co. Ltd.,
Montreal, P.Q.
(DBS - DI - CPMA)

Parke, Davis & Co. Ltd.,
Reno, Nevada,
U.S.A.

The Penslar Co.,
Tecumseh, Ontario.
(DBS - DI)

Pertussin Ltd.,
Montreal, P.Q.
(DBS)

Canadian Firm

Foreign Firm

x Pfizer Corp.,
Montreal, P.Q.
(DBS - DI - CPMA)

Pharmo Products Ltd.,
Toronto, Ontario.
(DBS - DI)

The Pinex Co.,
Toronto, Ontario.
(DBS - DI)

Lydia E. Pinkham Medicine Co.,
Cobourg, Ontario.
(DBS - DI)

x Pitman Moore of Can. Ltd.,
Toronto, Ontario.
(DBS - DI - CPMA)

x Poulenc Ltée,
Montreal, P.Q.
(DBS - DI)

Arthur N. Pratte Ltd.,
Montreal, P.Q.
(DBS - DI)

x Private Brand Packagers Ltd.,
Toronto, Ontario.
(DBS - DI)

Produits Gardo Ltée,
Waterloo, P.Q.
(DBS)

x Professional Sales Corp.,
(also listed as Professional
Pharmaceutical Corp.),
Montreal, P.Q.
(DI)
Distributor for -

Chas. Pfizer & Co. Inc.,
Brooklyn, New York,
U.S.A.

The Lydia E. Pinkham Medicine Co.,
Lynn, Massachusetts,
U.S.A.

Allied Laboratories Inc.,
Kansas City, Missouri,
U.S.A.

Société des Usines Chimiques
Rhône-Poulenc,
Paris, France.

Chester A. Baker Labs Inc.,
Boston, Massachusetts,
U.S.A.

Central Soya Co. Inc.,
Chicago, Illinois,
U.S.A.

Chicago Pharmacal Co.,
Chicago, Illinois,
U.S.A.

Lorvic Corp.,
St. Louis, Missouri,
U.S.A.

Shield Laboratories,
Detroit, Michigan,
U.S.A.

Syntex Chemical Co. Inc.,
New York, New York,
U.S.A.

and a few other firms.

Canadian Firm

Foreign Firm

W. T. Rawleigh Co. Ltd., Montreal, P.Q. (DBS)	
* Harry D. Reid Agencies, Toronto, Ontario. (DI) Distributor for -	Boots Pure Drug Co. Ltd., England.
	Aspro-Nicholas Ltd., England.
	Moore Medical Products Ltd., England.
* Rexall Drug Co. Ltd., Cooksville, Ontario. (DBS - DI)))) Rexall Drug Co.,) Los Angeles, California,) U.S.A.
* Riker Pharmaceutical Co. Ltd., Cooksville, Ontario. (DI)))
* Harold F. Ritchie & Co. Ltd., (See Beecham Products Ltd.) Leslie Robb Distributor, Toronto, Ontario. (DI) Distributor for -	Desitin Chemical Co., Providence, Rhode Island, U.S.A.
* Robert & Son Ltd., Montreal, P.Q. (DI) Distributor for -	Vitamin Products Co., Milwaukee, Wisconsin, U.S.A.
Roberts Biological Laboratory Ltd., Toronto, Ontario. (DBS - DI)	
* A. H. Robins Co. of Can. Ltd., Montreal, P.Q. (DI)	A. H. Robins Co. Inc., Richmond, Virginia, U.S.A.
Rolls & Darlington Ltd., Toronto, Ontario. (DBS - DI)	
* Rougier Inc., * (also Rodeca Inc.) Montreal, P.Q. (DBS - DI - CPMA)	
Row & Co., St. Stephens, New Brunswick. (DBS - DI)	
The Geo. H. Rundle & Son Co. Ltd., Windsor, Ontario. (DBS - DI)	The Geo. H. Rundle Co., Piqua, Ohio, U.S.A.
Robapharm (Canada) Ltd., St. Jerome, P.Q. (DBS - DI)	

Canadian Firm

Foreign Firm

Les Médicaments St. Germain, Montreal, P.Q. (DBS)	
Sandoz (Canada) Ltd., * Pharmaceutical Div., Dorval, P.Q. (DI - CPMA) (See also Mount Royal Chemicals Ltd.)	Sandoz Ltd., Basle, Switzerland.
* W. E. Saunders Ltd., London, Ontario. (DBS - DI - CPMA)	
* R. P. Scherer Ltd., Windsor, Ontario. (DBS - DI - CPMA)	R. P. Scherer Corp., Detroit, Michigan, U.S.A.
* Schering Corp. Ltd., (also White Labs. of Can. Ltd.) Montreal, P.Q. (DBS - DI - CPMA)	Schering Corp., Bloomfield, New Jersey, U.S.A.
The Scholl Mfg. Co. Ltd., Toronto, Ontario. (DI)	Scholl Mfg. Co. Inc., Chicago, Illinois, U.S.A.
Scientific Concentrates Ltd., Rouville, P.Q. (DBS)	
* G. D. Searle & Co. of Can. Ltd., Toronto, Ontario. (DBS - DI - CPMA)	G. D. Searle & Co., Chicago, Illinois, U.S.A.
Shaw Research, Omeme, Ontario. (DBS - DI)	
* Sherman Laboratories, Windsor, Ontario. (DI)	Sherman Laboratories, Detroit, Michigan, U.S.A.
Shirley Laboratories, Vancouver, British Columbia. (DBS)	
Dr. N. A. Sirois Enrg., Ste. Anne de la Pocatiere, P.Q. (DBS - DI)	
* Smith Kline & French Inter- American Corp., (also Franklin Laboratories), Ville St. Laurent, P.Q. (DBS - DI - CPMA)	Smith Kline & French Laboratories, Philadelphia, Pennsylvania, U.S.A.
* Smith & Nephew Ltd., Town of Mount Royal, P.Q. (DI)	Smith & Nephew Associated Co.'s Ltd., London, England.
Sorex Inc., Quebec, P.Q. (DBS - DI)	

Canadian Firm

Foreign Firm

* Specialty Pharmaceuticals Ltd.,
(subsidiary of Lyman's Ltd.)
Montreal, P.Q.
(DBS - DI)

* Springwood Pharmaceuticals Ltd.,
Saanichton, British Columbia.
(DBS - DI)

* E. R. Squibb & Sons of Can. Ltd.,
St. Laurent, P.Q.
(DBS - DI - CPMA)

E. R. Squibb & Sons Div.,
Olin Mathieson Chemical Corp.,
New York, New York,
U.S.A.

Standard Tabletting Co. Ltd.,
Toronto, Ontario.
(DBS)

B. C. Stanley Laboratories Ltd.,
Vancouver, British Columbia.
(DBS)

* Sterling Drug Mfg. Ltd.,
(Sterling Drug Products Ltd.)
(The Bayer Co. Ltd.)
Aurora, Ontario.
(DBS - DI)

Sterling Drug Inc.,
New York, New York,
U.S.A.

J. Stevens & Son Co. Ltd.,
(also associated Stevens Co.'s)
Toronto, Ontario.
(DBS)

Dr. F. Stafford & Son Ltd.,
St. John's, Newfoundland,
(DBS)

* R. J. Strassenburgh Co. of Can. Ltd., R. J. Strassenburgh Co.,
Toronto, Ontario. Rochester, New York,
(DI) U.S.A.

* Strong, Cobb, Arner, Strong, Cobb, Arner Inc.,
(formerly Strong Cobb of Can. Ltd. Cleveland, Ohio,
and The Arner Co. Ltd.) U.S.A.
Fort Erie, Ontario.
(DBS - DI - CPMA)

Super Vita Concentrates Inc.,
Montreal, P.Q.
(DBS)

Supreme Drug Ltd.,
Toronto, Ontario.
(DBS - DI)

Sutcliffe & Bingham of Can. Ltd.,
Toronto, Ontario.
(DBS - DI)

* Tailby-Nason Co. of Can. Ltd.,
Montreal, P.Q.
(DI)

Tailby-Nason Co.,
New York, New York,
U.S.A.

Templetons Ltd.,
Toronto, Ontario.
(DBS - DI)

Templetons Inc.,
Buffalo, New York,
U.S.A.

Canadian Firm

Foreign Firm

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| Unik Ltée,
Montreal, P.Q.
(DI)
Distributor for - | Martin H. Smith & Co.,
New York, New York,
U.S.A. |
| ✕ The Upjohn Co. of Can.,
Toronto, Ontario.
(DI - CPMA) | The Upjohn Co.,
Kalamazoo, Michigan,
U.S.A. |
| Urist Chemical Laboratories,
Vancouver, British Columbia.
(DBS) | |
| Valor Medica Inc.,
Montreal, P.Q.
(DBS - DI) | |
| ✕ Van Zant & Co. Ltd.,
Toronto, Ontario.
(DI) | McNeil Laboratories Inc.,
Philadelphia, Pennsylvania,
U.S.A. |
| Vick Chemical Inc.,
St. Thomas, Ontario.
(DBS - DI) | Vick Chemical Co.,
New York, New York,
U.S.A. |
| ✕ Vinant Ltd.,
Montreal, P.Q.
(DI) | Exclusive Canadian representative for
ten French laboratories. |
| ✕ Henry K. Wampole & Co. Ltd.,
Perth, Ontario.
(DBS - DI - CPMA) | Denver Chemical Mfg. Co.,
Stamford, Connecticut,
U.S.A. |
| ✕ Warner-Chilcott Laboratories Co. Ltd.)
Toronto, Ontario.
(DI - CPMA) |) Warner-Lambert Pharmacal Co.,
) Morris Plains, New Jersey,
) U.S.A.
) |
| ✕ Warner-Lambert Canada Ltd.,
Toronto, Ontario.
(DBS - DI) | |
| Warren Teed Can. Ltd.,
Toronto, Ontario.
(DI) | Warren Teed Products Co.,
Columbus, Ohio,
U.S.A. |
| The J. R. Watkins Co.,
Montreal, P.Q.
(DBS) | |
| ✕ Webber Pharmaceuticals Ltd.,
Toronto, Ontario.
(DBS - DI) | |
| ✕ Whitehall Laboratories Ltd.,
Toronto, Ontario.
(DI) | American Home Products Corp.,
New York, New York,
U.S.A. |
| Dr. White Medicine Co. Ltd.,
Winnipeg, Manitoba.
(DBS - DI) | |
| ✕ Chas. R. Will & Co. Ltd.,
London, Ontario.
(DBS - DI - CPMA) | |

Canadian Firm

American Firm

* Winley-Morris Co. Ltd.,
* (Veterinary Medical Supply Co.
of Can.
Agence-Medicale Nationale),
Montreal, P.Q.
(DI)

* Winter Laboratories Ltd.,
* (Empire Laboratories Ltd.
Dominion Pharmacal)
Toronto, Ontario.
(DI)

* Winthrop Laboratories of Can. Ltd., Sterling Drug Inc.,
Windsor, Ontario. New York, New York,
(DI - CPMA) U.S.A.

Harris Wondro Ltd.,
Calgary, Alberta.
(DBS)

* W. Lloyd Wood Co. Ltd.,
Toronto, Ontario.
(DI)
Distributor for -

American Apothecaries Co.,
Long Island, New York,
U.S.A.

Hynson, Westcott & Dunning,
Baltimore, Maryland,
U.S.A.

* John Wyeth & Brother (Can.) Ltd.,
Walkerville, Ontario.
(DBS - DI - CPMA)

American Home Products Corp.,
New York, New York,
U.S.A.

APPENDIX II

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"DOCTORS, DRUGS AND DRUG PROMOTION"

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The development and introduction of new therapeutic agents has followed a roughly exponential course over the past century, and as an inevitable result of such a process, the number of new agents introduced annually has now overwhelmed the average practising physician. This would be true even if only new chemical compounds were involved, and the problem is multiplied many times by mixtures and combinations. Each of these has its own trade name and tends to develop a vague but independent identity to which it rarely is entitled. The pharmaceutical industry has been responsible for the development and manufacture of many drugs which represent major therapeutic advances. Indeed, the advent of 'wonder drugs' has tended to delude both the medical profession and the public into believing that any new product represents a modern miracle. Unfortunately, relatively few new products contribute substantially to medical progress.

Rapid introduction of large numbers of new agents and combinations, and frequent delays in the publication of full information regarding their properties and effects, have combined to produce a situation in which even the full-time pharmacologist is hard pressed to keep abreast of developments. For the busy practitioner the situation has become impossible, and a majority no longer attempt personally to evaluate the data on new agents even when it is available. There is an increasing tendency to try new agents simply on the basis of drug-house literature. The volume of this material has expanded tremendously since the end of the war. It ranges from a few words on a blotter to elaborate, profusely illustrated booklets, and includes thousands of pages annually in the standard medical journals. Because it has come to play a major role in disseminating information on new drugs, the material prepared and distributed by pharmaceutical manufacturers must be carefully evaluated, and evaluated as advertising.

It is clear that the medical profession plays a major role in determining types and volume of drug advertising. In the hard-headed world of business, the type of promotion employed is determined by the response obtained. Journal advertising, direct mailing, free samples, business gifts such as pens or notebooks and various forms of entertainment all have been shown to increase sales. Obviously, if any of these forms of promotion were not heeded by the profession, it would soon disappear. However, it appears that the physician, ostensibly endowed with scientific scepticism, is as susceptible to the huckster's art as is the general public. 'Ethical' medical advertisements employ more technical terms than are used by the white-coated television 'doctor' extolling the latest mouthwash, but the approach employed in most medical advertising is identical.

Occasional brochures produced by some manufacturers contain relatively complete and reliable surveys of available information regarding an agent or preparation. These may contain considerable valuable material, but they are more difficult and time-consuming to read and require considerably more thought on the part of the physician than do the shorter, gaudier bits of advertising. Consequently, they frequently are neglected by the profession.

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This has been recognized by advertising departments, and such 'full coverage' brochures usually are sent only to a short, selected list of physicians.

A type of 'prestige' advertising requires special mention. Pharmaceutical manufacturers frequently put out booklets on specific disease entities or sponsor closed-circuit television programs which are primarily educational in nature. Some of these are excellent in content and presentation and provide a real service. However, they must be distinguished sharply from promotional material. The fact that a booklet contains an informative and reliable article on liver disease does not mean that the advertisements enclosed in the same cover also are reliable.

All promotional material, irrespective of its form or source, must be evaluated with a full appreciation of the role of advertising and of advertising personnel in the contemporary pharmaceutical industry. In the advertising business it is freely recognized that a major purpose, if not the major purpose, of advertising is to create a demand where no real need exists. This clearly is a factor in much drug advertising. New preparations which effectively fill a real need require little promotion. The first sulfonamides, penicillin, cortisone and more recently chlorothiazide needed no advertising to create a demand. Most of the promotional material is not prepared by, or even seen before publication by medical personnel. It is prepared by highly specialized promotional departments, which in many instances represent the effective controlling influence in a pharmaceutical organization. These departments have available extensive analyses of all drug sales from which they evaluate sales trends and determine marketing policy.

The chemistry of medicinal compounds has advanced to the point where it generally is possible for a group of good chemists to produce on request a compound closely related to a known drug which has comparable activity and avoids patent infringement. This 'me-too' agent usually does not have important advantages over its predecessor, and indeed may be somewhat inferior. It is necessary only that it be different and that it have comparable activity. The advertising department will 'discover' and establish its superiority. A mixture may be even more easily and rapidly prepared to meet sales requirements. If the components previously have been cleared for sale, very little information regarding its therapeutic or toxic properties is required prior to marketing. Given adequate promotion, such a mixture can be highly profitable. Polypharmacy of this type represents a large step back towards the complex Latin prescriptions of a century ago, with the added disadvantage that the drug house rather than the physician determines the composition. These multiple-drug preparations expose patients to an increased number of toxic reactions, particularly of the sensitivity type. Multiple vitamin preparations containing folic acid are examples of mixtures which do serious harm, in this case by promoting neurological damage when given to persons with an unsuspected pernicious anaemia. Drug houses and physicians bear equal guilt in the use of such mixtures.

Certain therapeutic areas have become so large and lucrative that major drug houses rarely can afford to ignore them. A new product does not have to have any well-established advantages to take over 5 or 10% of the sales volume in many fields, and inasmuch as a number of types of therapeutic agents now have annual North American sales in excess of \$50,000,000, it obviously is unnecessary for a company to await the development of a really superior product before entering the competition. This is particularly true because the subjective nature of responses and/or the chronicity of many disease processes which have attracted recent attention (atherosclerosis, rheumatoid arthritis, allergic reactions, mental disease, etc.) are such as to make it impossible to draw definitive conclusions regarding therapeutic efficacy until a drug has been in use for years. It is clear that substantial profits frequently can be realized from even a very inadequate product long before any clear evaluation of effectiveness is possible.

The above considerations emphasize the necessity of carefully scrutinizing promotional material. Unfortunately, there is no simple and

reliable formula for sorting useful information from that which is useless or misleading. However, certain factors warrant special attention.

A major consideration in the adoption of any new product is toxicity. It is axiomatic that every drug has some toxicity, and the common promotional statement that a given product has 'low toxicity' or has not produced this or that specific type of toxic reaction is of limited significance. It is much more important to know the types of toxicity which may occur. Advertisements rarely carry this information. Detail men may be asked for and sometimes are helpful in obtaining the desired data. However, this very useful information frequently is not included in the routine promotional material which they receive, and it may take them some time to obtain it. A related problem is presented by advertisements which include a considerable discussion of toxic reactions, but fail to mention those which may be of major concern. Current advertisements for new adrenal steroids are illustrative. They uniformly refer to decreased salt retention as an advantage, but say nothing about suppression of pituitary-adrenal function or decreased resistance to infection-major hazards in the use of any agent of this type. In the absence of definitive information, it usually is correct to assume that the new agent is at least as dangerous as its predecessors with respect to the unmentioned properties.

One always must be sceptical of claims regarding the low toxicity of new drugs. Reports of toxicity are slow to appear. This is accentuated by the current tendency to administer multiple agents simultaneously, which often makes it difficult to be sure which is responsible for a given reaction. In addition, reactions which involve induced sensitivity are not prominent until an agent has had a considerable period of widespread use. Chloramphenicol provides an example of a common pattern of toxicity reports. No clear cases of bone marrow damage due to this drug were reported for several years after its introduction. Finally, a few definite cases were reported, followed by a considerable number of reports, which brought about a sharp reduction in its use. More recently, this antibiotic has again been employed more extensively, but without a parallel increase in reports of toxicity. However, the paucity of published reports of toxic reactions cannot be taken as reliable evidence that the drug has changed or even that physicians have become more adept in its use. It may be simply an expression of the well-known fact that observers are disinclined to publish reports of additional cases of a well-known toxic reaction.

A favourite advertising statement which must be interpreted with caution is that a new drug or preparation is 'more potent' than its predecessors. Unfortunately, the term 'potency' appears to have developed almost mystic connotations of effectiveness, of ability to do things which a less potent drug cannot accomplish. In advertisements it is meant to suggest therapeutic superiority where the manufacturer cannot make this claim directly. 'Potency' has no such implications. It simply refers to the dose required to produce a given response. Except where previous preparations were too bulky to be easily administered, potency per se is of little significance. A recent advertisement for a new steroid stated that it had 'enhanced potency without corresponding increase in side reactions in therapeutic doses'. The enhanced potency means simply that the therapeutic doses are reduced, and this statement should properly read 'same therapeutic effects, same toxic reactions'. One suspects that this is not the connotation intended, or how the statement actually was read by the majority of recipients.

Advertisements which make frequent references to published studies pose special problems. They are definitely superior to those without references because they do provide the physician with a basis for checking on the statements made. However, the presence of references does not guarantee the validity of generalizations made from them. A thorough check for reliability requires access to reasonable library facilities and considerable work. However, simple attention to the journals quoted may provide considerable information. Anyone even moderately acquainted with the medical literature is aware of the fact that studies published in some journals provide much more reliable information on the average than do those published in others. Indeed, some journals have become so uncritical of the material which they publish that they are regularly utilized for the

publication of 'studies' which are purely promotional. A good journal does not necessarily assure good work, but it considerably increases the chances of reliability.

Selection of references is an obvious method of obtaining unjustifiably favourable opinions, as is the quotation of phrases or sentences out of context. The former is the more difficult to detect and may not be obvious except to one thoroughly familiar with the literature on the subject in question. In evaluating papers quoted in drug promotion, it is very important to note doses and dosage schedules. For example, the full significance of a recent promotional effort, which provided references to both efficacy and lack of toxicity, was not apparent until it was noted that the doses used in studies quoted to demonstrate lack of toxicity were considerably lower than those used to substantiate efficacy.

Clues to the real significance of the references quoted may sometimes be found in the advertisement itself. One advertisement extolling the merits of a new nitrite 'coronary dilator' contained essentially the following points, each with references. (1) Many clinical observations have demonstrated nitroglycerin to be the most consistently useful agent in angina pectoris. (2) An agent with comparable activity but with a longer duration of action would represent a real advance in the treatment of this condition. (3) Our nitrite has a considerably longer vasodilator action than does nitroglycerin. Therefore, it is the agent of choice in the treatment of angina pectoris. The first two points were documented by references to well-known authorities, the third by an obscure publication showing that the drug in question produced a somewhat more prolonged hypotension in anaesthetized cats. Although a casual glance at the list of references would indicate substantial authoritative backing for the claim that the new agent represented a major advance in the therapy of angina pectoris, more careful scrutiny of the references presented failed to reveal any evidence that the drug in question had ever been found to be of value in this condition, or that any of the authorities quoted to substantiate the first two points had tested or even heard of it.

Advertisements quoting what appear to be relatively reliable reports of clinical improvement resulting from the administration of a given preparation still require careful scrutiny, coupled with a clear appreciation of the natural history of the disease process in question. Favourable responses to therapy in cases of acute peptic ulcer are illustrative. It is well known that this is a cyclic disease in which the patient most commonly consults his physician during a relapse. Most will improve without therapy, and improvement can be hastened somewhat by almost any type of treatment including simple rest, mild sedation, any one of several diets, antacids, 'antispasmodics' or just careful attention and concern on the part of the physician. Obviously, under these circumstances, the simple observation that 23 of 25 patients improved on a given preparation means little. Data on improvement from an acute exacerbation of this disease are meaningful only if carefully compared with the improvement induced by some standard treatment under controlled, 'double-blind' conditions. A more difficult problem in the management of patients with peptic ulcer is the prevention of recurrences, and any drug which could prevent recurrences would represent a real therapeutic advance. However, this critical point is almost never mentioned in advertisements. This is not due to failure of advertisers to recognize the importance of this aspect of the disease, but to the inability of their product to do anything about it. In the absence of information regarding recurrences, one can safely conclude that the new preparation does not alter them, and therefore has no major advantages over any one of a great number of older and usually much cheaper forms of therapy.

The interpretation of advertisements for mixtures presents special problems. One of the first questions to ask is whether the combination is really logical. The advertiser frequently counts on the physician's failing to look below the surface in this regard. Adrenal steroids are well known to produce or reactivate peptic ulcers and it is superficially logical to combine them with an antacid. However, with the usual therapeutic regimens, the increase in acidity and the decrease in resistance to erosion induced by the steroids is essentially continuous, and in any case, the maximum

effect of a given dose is exerted several hours after oral administration, long after any antacid administered with it has left the stomach. These considerations make it obvious that combination of steroid and antacid in the same tablet will be of little value and may actually be very dangerous in leading to a false sense of security.

One clue to the real value of a drug may be obtained by noting the combinations which receive major attention in advertisements. It is well known that mild sedation is useful in the management of patients with peptic ulcer. Phenobarbital is a valuable drug for this purpose and the mild 'tranquilizers' have been utilized as a more expensive method of obtaining the same effect. When a manufacturer pushes his 'antispasmodic' or 'antisecretory' compound in combination with phenobarbital or a 'tranquilizer', it suggests that he does not have much confidence in the efficacy of his 'primary' agent, and the prescribing physician may well treat it with even greater scepticism. Drug combinations frequently are justified on the basis of convenience to the physician and patient. However, in the final analysis, their major contributions are to preclude independent evaluation of the effects of the constituents and adjustments of the relative dosages to meet the needs of specific patients.

A minimum and absolute requirement in the utilization of a mixture is to know what it contains. To stress this point may appear to insult the practising physician, but experience has shown such caution to be necessary. A casual local survey during the past year revealed the following: (1) A majority of physicians utilizing a 'new' and effectively advertised analgesic did not know that it is simply the standard APC (acetylsalicylic acid, phenacetin and caffeine) plus a little barbiturate. (2) Several physicians did not know the composition of the mixed electrolyte solutions they ordered by a simple number or letter designation. As a result, we have seen two recent patients with post-traumatic oliguria receiving potassium-containing solutions. Both died of potassium intoxication before renal function was reestablished. (3) A mixture of antimalarials and a steroid was administered for a dermatological condition without any appreciation of the amount of steroid in the mixture, and consequently without any provision for gradual withdrawal to allow recovery of suppressed endogenous pituitary-adrenal function. These examples, without further comment, should adequately emphasize the absolute necessity of knowing the exact composition of any mixture employed.

The above discussion may paint a rather bleak and hopeless picture of the essential impossibility of the busy practitioner adequately evaluating the drugs and drug advertising to which he is exposed. It would not be honest and accurate to leave any other impression. The advertising pressures and the multitude of new agents and combinations which do not represent real advances in therapy have combined to produce a situation with which the practitioner cannot cope satisfactorily. The drug houses themselves should take the lead in reversing the current trend by introducing new therapeutic agents and mixtures only when these provide advantages of considerable magnitude over anything previously available, and by making their advertisements less promotional and more informative. A major step in this direction would be to give their medical and research departments more control over advertising policy and content. Many of these departments contain well-qualified men who currently are embarrassed by some of the products and advertising claims of their own companies, which they may refuse to defend in conversations with their professional colleagues. However, much of the responsibility rests on the medical profession, whose obligation to the public requires active protest against current promotional practices. This can be expressed in many ways, but, in the long run, the most effective protest is refusal to prescribe agents for which real advantages have not been proved and on which complete information is not provided. For the present, the practitioner can considerably improve his utilization of new drugs, or at least minimize his mistakes, by developing a high degree of scepticism. This can be actively expressed along the following lines.

1. Be slow to accept any new agent. In dealing with new drugs it is particularly important to remember the principle - 'First, do no harm.' Very few new drugs represent major advances in therapy, and those which do

will quickly show their real value. You will do your patients little harm by delaying the acceptance of new agents, and you may save them from dangerous side effects, from unjustified reliance on new drug therapy to the exclusion of more reliable, if less spectacular measures, and if nothing else, from the unnecessary expenditure of considerable sums of money. New drugs are never cheap.

2. If you do wish to consider the early use of new agents, select one at a time, carefully evaluate all of the available data on it, and reject its use unless there is clear evidence that it represents a real therapeutic advance. Thorough investigation of a few agents will always prove to be more profitable than cursory examination of many. It is desirable to select products for investigation from among those for which the manufacturer has provided relatively complete bibliographies. This simplifies the task, provides some selection on the basis that full information is more apt to be provided for those products in which the manufacturer himself has confidence, and finally, in the long run, such selection may induce manufacturers to provide more adequate information on their products.

3. Be particularly sceptical of mixtures, of new dosage forms and of compounds closely related to established agents. There is still much truth in the concept that how you use a drug is more important than what drug you use. Proper use requires personal familiarity with both therapeutic and toxic responses, which rarely is possible if one switches preparations at frequent intervals.

4. Finally, and most important, consciously maintain your prerogatives as a physician to decide on the basis of your own training, reading and experience what drugs to administer, and in what forms and dosages. It is appalling to note the extent to which drug houses and patients now determine therapeutic practices. Neither is qualified for this role. Certainly the mother is not qualified to decide whether her child should receive an antibiotic for his sore throat, and the drug manufacturer is no more competent to decide, through a fixed-ratio mixture, the relative doses of two or more drugs to be administered to a given patient.

Drug advertisements and detail men can be useful sources of information in the harassing process of keeping up with new developments in drug therapy. However, if one does not have the time, the facilities or the inclination personally to evaluate their wares, less harm will be done if they are ignored completely. Remember that advertising is advertising."

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